PART 1

EXHIBITS TO DECLARATION OF SARAH BLAINE

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

11:00:35

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CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually, and as Guardian ad litem of the Infant, ROSIE GROSSBAUM,

Plaintiffs,

-against-

Index No. 07-CV-359

GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE, and NEW YORK UNIVERSITY HOSPITALS CENTER, both Corporations of the State of New York, ABC CORPORATIONS: 1-10 and John Doe

Defendants.

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132-26 Conduit Avenue
Jamaica, New York
May 4, 2010
10:30 a.m.

DEPOSITION of CHARLES STROM, M.D., PhD., an expert witness on behalf of the Plaintiff herein, taken by the Defendants pursuant to Article 31 of the Civil Practice Law and Rules of Testimony, and Notice, held at the above-mentioned time and place before Valerie Cannata, Shorthand Reporter and Notary Public of the State of New York.

C. STROM, M.D., PhD.
THE WITNESS: Charles Martin Strom. 11:02:42 11:02:43
THE REPORTER: What is your current address? 11:02:46 11:02:46
THE WITNESS: [redacted], San Clemente, California, 92673. 11:02:47 11:02:51 11:03:02
MR. LEUCHTMAN: Dr. Strom, my name is Stephen Leuchtman. I represent Genesis Genetics and Mark Hughes. We're here to take your discovery deposition today. The only -- there are a lot of admonitions that can be set forth before a deposition. The only one or two that I'm concerned about are first, I don't want you to engage in speculation, guess or conjecture. Estimates are fine, as long as you say they are estimates, but guesses are not permitted in depositions; or at least I don't want you to engage in any guesswork. 11:03:04 11:03:06 11:03:07 11:03:10 11:03:12 11:03:14 11:03:18 11:03:21 11:03:23 11:03:26 11:03:30 11:03:33 11:03:37 11:03:39
The other thing is if you don't understand the question, please tell me and I will rephrase it. Otherwise 11:03:40 11:03:42 11:03:44

C. STROM, M.D., PhD.
anybody reading the transcript or seeing the videotape has the right to assume that you understood the question and answered it, okay? 11:03:46 11:03:49 11:03:51 11:03:53
THE WITNESS: Yes. 11:03:55
MR. LEUCHTMAN: And that's the other thing, please answer verbally so the Court Reporter can get it down. 11:03:56 11:03:59 11:04:02
THE WITNESS: Yes. 11:04:04
MR. LEUCHTMAN: You have in front of you what appear to be file materials. May I see those, please? 11:04:05 11:04:07 11:04:09
THE WITNESS: Yes. 11:04:12
(The Witness produced documents.) 11:04:18
MR. LEUCHTMAN: Thank you. 11:04:19
THE WITNESS: You're welcome. 11:04:20
MR. LEUCHTMAN: I'd like the file to be marked as an exhibit. We can do it now or later on. 11:05:07 11:05:08 11:05:12
(Defendant's Exhibit A was marked for identification.) 11:05:12 11:05:15
EXAMINATION BY MR. LEUCHTMAN: 11:05:15 11:05:15
Q. Is this your entire file? 11:05:16

C. STROM, M.D., PhD.
A. No. 11:05:18
Q. What else is contained within your file? 11:05:18 11:05:21
A. I'm sorry. I have no file. This is a stack. This is my stack. 11:05:22 11:05:23
Q. Is this your entire stack? 11:05:28
A. At the moment, yes. 11:05:31
Q. What do you mean by at the moment? 11:05:32 11:05:35
A. It's what I have now. 11:05:36
Q. Is it all the materials you've received on this case? 11:05:37 11:05:40
A. Yes. 11:05:41
Q. So the only deposition you've been provided with is that of Mark Hughes? 11:05:42 11:05:43
A. What's in that stack. I was -- actually, I was given an electronic copy of the deposition of Gary Cutting that I read on my computer, but there's no hard copy of that. 11:05:46 11:05:48 11:05:53 11:05:57
Q. Have you gotten anybody else's deposition transcripts? 11:06:01 11:06:03
A. No. 11:06:04
Q. You don't have Lucciardi (phonetic) or anybody from N.Y.U.? 11:06:04 11:06:08

C. STROM, M.D., PhD.
A. No. 11:06:09
Q. And you have not read any transcript of any of the other parties, including the Plaintiffs, Menchen Grossbaum and Chaya Grossbaum? 11:06:09 11:06:12 11:06:13 11:06:16
A. Correct. 11:06:17
Q. Would you tell us for the record what articles you have in your stack? Feel free to refer to them. 11:06:18 11:06:24 11:06:28
(The Witness perused the exhibit.) 11:06:34 11:06:35
A. I have several articles and then I had several abstracts that I had printed from Med Line. Do you want everything the whole, everything? The title and all the authors? That will take forever. 11:06:35 11:06:54 11:07:03 11:07:08 11:07:10
Q. A shorthand reference is fine. I don't think it will take forever. 11:07:13 11:07:15
A. How about Goosens, G-O-O-S-E-N-S, et. al. 11:07:15 11:07:22
Q. That's fine. 11:07:24
A. Improving Clinical Preimplantation Genetic Diagnosis... The Journal of Molecular Reproduction, volume 9, 11:07:24 11:07:30 11:07:42

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number 9, pages 559 to 567, 2003. 11:07:48
Thornhill and Snow, Journal of 11:07:54
Molecular Diagnostics, volume 4, number 1, 11:07:59
February, 2002. 11:08:06
MR. LEUCHTMAN: That's a 11:08:07
sufficient reference. 11:08:08
A. Rechitsky, R-E-C-H-I-T-S-K-Y, 11:08:10
et. al. Journal of Assisted Reproduction 11:08:16
and Genetics, volume 16, number 4, pages 11:08:20
192 to 199. 11:08:27
The same Rechitsky et. al., 11:08:30
Fetal Cells and Fetal DNA in Maternal 11:08:37
Blood, New Developments for a New 11:08:42
Millennium, edited by the 11th Fetal Cell 11:08:47
Workshop, Basel, 2000. 11:08:52
Moutou, M-O-U-T-O-U, et. al. 11:08:59
European Journal of Human Genetics, 2002, 11:09:04
volume 10, 231 to 238. 11:09:11
Vrettou, V-R-E-T-T-O-U, et. al. 11:09:17
Molecular Human Reproduction, volume 8, 11:09:20
number 9, pages 880 to 886. 11:09:24
Eftedal, E-F-T-E-D-A-L, et. al. 11:09:30
Molecular Human Reproduction, volume 7, 11:09:34
number 3, pages 307 to 312, 2001. 11:09:39

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Harper and Bui, B-U-I, Best 11:09:46
Practice Research Clinical Obstetrics and 11:09:57
Gynecology, 2002, October 16th, volume 5, 11:10:03
659 to 70. 11:10:09
Verlinsky, V-E-R-L-I-N-S-K-Y, 11:10:14
et. al. 11:10:17
Q. These are abstracts you're 11:10:19
referring to now? 11:10:21
A. Right. Of articles. 11:10:22
Q. Yes. 11:10:22
A. These are published articles. 11:10:24
Reproductive Biomed Online, 2002. 11:10:25
January to February, volume 4, number 1, 11:10:29
38 to 42. 11:10:34
Rechitsky, et. al, Molecular 11:10:38
Cellular Endocrinology, 2001, October 22nd 11:10:45
supplement, S 65 to 8. 11:10:49
Apessos, A-P-E-S-S-O-S, A 11:10:59
Prenatal Diagnosis, 2001, June, volume 21, 11:11:04
number 6, 504 to 11. 11:11:11
Dreesen, D-R-E-E-S-E-N, et. al. 11:11:17
Molecular Human Reproduction, 2000, May, 11:11:21
volume 6, number 5, 391 to 396. 11:11:27
Rechitsky again, et. al. 11:11:34

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Journal of Assisted Reproduction in 11:11:38
Genetics, 1999, April, volume 16, number 4, 11:11:42
192 to 198. 11:11:48
Again Rechitsky et. al., 11:11:52
Journal of Assisted Reproductive in Genetics, 11:11:54
1998, May, volume 15, number 5, 253 to 11:12:02
257. 11:12:06
Q. Is there any other literature 11:12:06
that forms the basis of your opinion besides the 11:12:08
ones in your stack there that you just 11:12:13
identified for the record? 11:12:14
A. No. 11:12:15
Q. Now, did you ask Mr. Stein for 11:12:16
any materials that you have not received? 11:12:27
A. No. 11:12:29
Q. Do intend to do any further 11:12:30
work on this case? 11:12:33
A. Yes. 11:12:35
Q. What do you intend to do? 11:12:35
A. Whatever I'm asked. 11:12:37
Q. You have authored a report in 11:12:38
this case? 11:12:44
A. Yes. 11:12:44
Q. Does that report contain all of 11:12:45

C. STROM, M.D., PhD.

your opinions? 11:12:47
MR. STEIN: Objection to the 11:12:48
form of the question. 11:12:49
BY MR. LEUCHTMAN: 11:12:49
Q. About this case that you expect 11:12:51
to offer at trial? 11:12:53
A. I can't speculate. 11:12:54
Q. I didn't ask you to speculate. 11:12:55
A. You asked me to speculate what 11:12:56
you might do at trial. 11:12:58
Q. I asked what you intend to do 11:13:00
at the present time at trial? 11:13:02
A. I have no intention to do 11:13:03
anything at trial. I will ask the questions that 11:13:04
I am answered at trial. 11:13:04
Q. Or vice versa. 11:13:04
A. I will answer the questions that 11:13:06
I am asked at trial. 11:13:07
Q. Have you reviewed any 11:13:09
information about Mark Hughes or Genesis 11:13:11
Genetics other than in your stack or 11:13:15
involving this case? 11:13:17
A. No. 11:13:17
Q. You've expressed opinions in 11:13:18

your report about things that the Grossbaums were advised by Dr. Hughes and others, correct? 11:13:23 11:13:25 11:13:29

A. I reviewed his note from his telephone conversations, yes. 11:13:29 11:13:34

Q. All right. 11:13:36

A. Conversation. 11:13:40

Q. And you expressed opinions in your report as to the adequacy of advice given to the Grossbaums and how they would have understood that advice? 11:13:41 11:13:44 11:13:49 11:13:52

A. Yes. 11:13:54

Q. Why then did you not seek to read their transcripts as to what they were told and what they understood from their perspective? 11:13:54 11:13:56 11:13:59

A. I did not choose what I sought. I accepted the packet from Counsel and I reviewed it. 11:14:02 11:14:05 11:14:08

Q. You knew their depositions had been taken, didn't you? 11:14:09 11:14:12

A. No, I didn't. 11:14:13

Q. Didn't you suspect their depositions had been taken? 11:14:14 11:14:18

A. Never occurred -- no. 11:14:20

Q. Did you ask whether their depositions had been taken? 11:14:21 11:14:23

A. No. 11:14:23

Q. You weren't interested in their perspective on what they were told, how they understood it and how they processed that information then? 11:14:23 11:14:25 11:14:28 11:14:32

A. I wasn't interested or not interested. I reviewed the materials I was given to review. 11:14:33 11:14:36 11:14:40

Q. And if I were to tell you that before the expert part of this deposition, there were nine depositions of this case there were nine depositions taken in this case. You've read one of those depositions, correct? The one of Dr. Hughes? 11:14:40 11:14:42 11:14:45 11:14:48 11:14:51 11:14:54

A. Two. And the one from Dr. Cutting. 11:14:56 11:14:58

Q. That was a tenth deposition; of the other eight, various other N.Y.U. employees and the Grossbaums, you haven't read any of those depositions. 11:14:59 11:15:01 11:15:04 11:15:06

A. That's correct. 11:15:06

Q. You haven't asked for any of 11:15:07

those depositions. 11:15:07

A. That's correct. 11:15:09

Q. And Mr. Stein has not provided you with any of those transcripts? 11:15:09 11:15:12

A. That's correct. 11:15:14

Q. And you're telling us you didn't suspect that others were deposed in this case, even though N.Y.U. is a party defendant? 11:15:15 11:15:17 11:15:20 11:15:22

A. It's none of my business. 11:15:23

Q. What is your business, then? How would you define it in this case? 11:15:27 11:15:30

A. I was asked to give an opinion based on these facts and I was sent a packet and I reviewed it and I gave my opinion. 11:15:30 11:15:32 11:15:34 11:15:37

Q. As a scientist, don't you want to know the entire universe of what might comprise that opinion? 11:15:38 11:15:41 11:15:46

A. I know that there's a difference between law and science and in law, you do what you're told. 11:15:47 11:15:49 11:15:50

Q. How many depositions have you given before today? 11:15:53 11:15:55

A. Maybe a dozen or so. 11:15:56

Q. As an expert witness? 11:15:58

A. Some as expert witness, some in criminal trials as an expert witness, so all as an expert witness. 11:16:00 11:16:02 11:16:07

Q. So you've given about a dozen depositions? 11:16:08 11:16:11

A. Give or take, yes. 11:16:11

Q. Have any of those been P.G.D. I.V.F. cases? 11:16:13 11:16:20

A. No. 11:16:21

Q. Have any of the cases where you've given depositions been non P.G.D., non I.V.F. cases involving cystic fibrosis? 11:16:25 11:16:37 11:16:41

A. No. 11:16:46

Q. What has been the subject matter of first of all depositions in medical legal cases as opposed to criminal cases where you have offered opinions? 11:16:47 11:16:50 11:16:53 11:16:57

A. I have testified in several child abuse cases as a practicing pediatrician. I have testified in a wrongful birth due to maternal serum screening. I've done several depositions in forensic cases 11:16:58 11:17:01 11:17:06 11:17:11 11:17:18

regarding DNA evidence admitted in courts 11:17:21
and criminal trials. 11:17:25
Q. The wrongful birth case, where 11:17:27
was that? 11:17:30
A. The wrongful birth was in 11:17:30
Chicago. 11:17:33
Q. Were you an expert witness or a 11:17:34
party in that case? 11:17:36
A. I was an expert witness. 11:17:37
Q. For the plaintiff or the defendant? 11:17:39
A. Plaintiff. 11:17:41
Q. In civil cases, how many times 11:17:41
have you been asked by percentage to 11:17:50
review cases for the plaintiff as opposed 11:17:53
to for the defendant? 11:17:56
A. More for defendants than 11:17:57
plaintiffs. 11:17:59
Q. You've given twelve depositions, 11:18:00
give or take. How many times have you 11:18:06
testified at trial? 11:18:08
A. Perhaps four or five. 11:18:09
Q. In what states? 11:18:13
A. All in Illinois. 11:18:18
Q. What percentage, as of 2010, of 11:18:20

your time is spent doing what we might call 11:18:32
forensic work? 11:18:35
A. Zero. 11:18:36
Q. Well, it can't be zero, you're 11:18:37
doing it now. 11:18:40
A. In the last ten years, I've 11:18:41
spent two hours, so it's close to zero. 11:18:43
Q. You spent two hours on this 11:18:46
case? 11:18:48
A. However time I spent. 11:18:48
Q. How much time have you spent? 11:18:49
A. Probably five hours. So five 11:18:52
hours divided by ten years is still close to 11:18:54
zero, but not zero. 11:18:58
Q. What do you charge as an 11:18:59
expert? 11:19:02
A. Five hundred dollars an hour. 11:19:03
Q. Is that for review and 11:19:04
deposition and trial testimony or is it 11:19:06
more for testifying? 11:19:08
A. It's more for deposition and 11:19:09
trial. 11:19:13
Q. What is it for deposition and 11:19:13
trial? 11:19:14

A. Deposition it's two thousand 11:19:14
dollars for four hours. If it's travel involved, 11:19:17
it's three thousand dollars a day. 11:19:21
Q. And for trial? 11:19:30
A. Same. Three thousand dollars a 11:19:31
day if travel is involved, two thousand dollars a 11:19:32
day if not. 11:19:37
Q. What percentage of your income 11:19:37
is derived from forensic work? 11:19:39
A. Zero. Excuse me; .001. 11:19:43
Q. Now, I'm looking at your 11:19:49
curriculum vitae and it covers various 11:19:54
faculty position, grants, memberships, et 11:19:57
cetera, but I don't see a chronology of 11:20:00
employment that I can follow. Let's do 11:20:02
that working backwards from Quest 11:20:06
Diagnostics. When did you start at Quest 11:20:09
Diagnostics? 11:20:09
A. I started in October, 2000. 11:20:09
Q. At what location? 11:20:11
A. In San Juan Capistrano, 11:20:13
California, where the swallows return. 11:20:18
Q. According to your C.V., from 11:20:23
October, 2000, to June, 2002, you were 11:20:26

the medical director molecular genetics 11:20:29
and biochemical genetics laboratories at 11:20:34
Quest. And then from June, 2002, to the 11:20:38
present, medical director, genetic testing 11:20:41
center. Can you describe those two 11:20:45
functions? Starting first with the one 11:20:48
you did from October of 2000, to June of 11:20:49
2002, what did you do as molecular 11:20:52
genetics and biochemical genetics medical 11:20:52
director? 11:20:56
A. Genetics at San Juan Capistrano 11:20:56
is divided into at that time three departments; 11:20:59
cytogenetics and molecular genetics and 11:21:03
biochemical genetics. I was the highest 11:21:11
ranking member of both the molecular 11:21:13
genetics department and the biochemical 11:21:19
genetics department. I was responsible 11:21:21
for all medical consultation, quality 11:21:22
assurance, all licenses, the research and 11:21:25
development program and obviously the 11:21:29
people in the laboratory reported up to 11:21:32
me. 11:21:34
I reported up to my boss, who 11:21:35
was the medical director of the genetic testing 11:21:37

center. 11:21:41
Q. Who was your boss? 11:21:41
A. Dr. Beverly White. 11:21:42
Q. During that period of time, did 11:21:44
Quest do P.G.D.? 11:21:47
A. No. 11:21:49
Q. How did your responsibilities 11:21:50
change when in June of 2002 you became 11:22:00
the medical director of the genetic testing 11:22:04
center? 11:22:10
A. That was a promotion, so I got 11:22:10
my boss's job and she retired. Actually, she 11:22:12
reported to me for a period of time. 11:22:18
Q. During that period of time, did 11:22:19
you do any P.G.D. or did the lab? 11:22:21
A. No. 11:22:23
Q. So you have not had hands-on 11:22:24
experience or directorial experience with 11:22:28
preimplantation genetics diagnosis since 11:22:33
October, 2002, or before? 11:22:38
A. That's correct. 11:22:40
Q. While you were at Quest, up to 11:22:50
today, have you had teaching responsibilities at 11:22:53
any university? 11:22:56

A. I teach -- I have a faculty 11:22:58
appointment at U.C.S.D. I teach intermittently 11:22:59
there and I also obviously give lectures across 11:23:06
the country. 11:23:09
Q. What do you teach at U.C.S.D.? 11:23:10
A. Everything genetics. 11:23:12
Q. Does this touch on P.G.D.? 11:23:15
A. Sometimes. 11:23:18
Q. What percentage of your 11:23:29
teaching responsibilities involve preimplantation 11:23:31
genetic diagnosis? 11:23:34
A. Probably less than five 11:23:34
percent. 11:23:36
Q. So it's fair to say that during 11:23:41
the time that this case unfolded, which is in 11:23:43
early 2004, primarily, you were not 11:23:49
involved either as a director of a P.G.D. 11:23:54
lab, hands-on with P.G.D. or teaching 11:23:58
P.G.D. to any significant extent? 11:24:03
MR. STEIN: Objection to the 11:24:05
form of the question. 11:24:06
A. No. That wouldn't be true 11:24:07
anyway. 11:24:09
Q. Why not? 11:24:09

A. Because my teaching 11:24:10
responsibilities are different than my 11:24:11
lecturing. 11:24:14
Q. Okay. 11:24:15
A. I lecture around the country 11:24:16
and often give talks on preimplantation 11:24:19
genetics. 11:24:23
Q. In a university setting, your 11:24:23
teaching is less than five percent of P.G.D.? 11:24:26
A. Yes. 11:24:31
Q. How much time do you spend 11:24:32
going around the country lecturing about P.G.D., 11:24:34
per se? 11:24:36
A. About two or three percent of 11:24:36
my time. 11:24:38
Q. Was this true in 2004? 11:24:39
A. Probably more so in 2004. 11:24:44
Q. How much more so? 11:24:47
A. I don't know. 11:24:49
Q. Less than ten percent? 11:24:50
A. I don't know. 11:24:51
Q. Less than 25? 11:24:52
A. I don't know. I just don't 11:24:54
remember. 11:24:56

Q. Well, give me a ballpark 11:24:57
estimate, not a guess. 11:24:58
A. I'm sorry, I just don't 11:24:59
remember. 11:25:01
Q. At all? 11:25:01
A. At all. It's a long time ago, 11:25:02
for me. 11:25:06
Q. So you probably don't remember 11:25:06
the standard of care for preimplantation 11:25:12
genetic diagnosis back in 2004 either? 11:25:15
A. I remember it very well. 11:25:18
Q. But you don't remember how much 11:25:20
of your lecture time was devoted to P.G.D.? 11:25:22
A. No, I don't remember. 11:25:26
Q. Was it less than half then? 11:25:27
A. I don't remember. 11:25:31
Q. When you went to Quest 11:25:34
initially, what were your responsibilities? I 11:25:35
think you started to tell me. 11:25:37
A. I told you. 11:25:39
Q. You did tell me. All right. 11:25:39
What are they now? 11:25:41
A. Now I oversee all of the 11:25:42
genetic testing that goes on in San Juan 11:25:47

Capistrano. 11:25:50
Q. And again, just to reiterate, 11:25:50
you do not now do P.G.D. at Quest and you 11:25:53
have not ever done P.G.D. at Quest? 11:25:56
A. Correct. 11:25:58
Q. Previous to Quest, you worked 11:25:58
for Reproductive Genetics Institute in 11:26:03
Chicago? 11:26:08
A. No. That's actually not 11:26:08
correct. 11:26:10
Q. It is, but maybe not directly 11:26:11
previous? 11:26:13
MR. STEIN: Let's not argue, 11:26:14
please. 11:26:16
A. I worked for Illinois Masonic 11:26:16
Medical Center as the director of genetics in the 11:26:19
department of obstetrics and gynecology 11:26:24
with co-appointments in the department of 11:26:27
pathology and the department of pediatrics. I 11:26:30
also held a nonpaid appointment as the 11:26:35
medical director and the director of the 11:26:38
DNA laboratory at the Reproductive 11:26:41
Genetics Institute in Chicago. 11:26:46
Q. What years were you connected 11:26:49

with Illinois Masonic Medical Center? 11:26:51
A. You have my C.V. I'm not good 11:26:54
with years or dates. 11:26:57
Q. You don't remember? 11:27:02
A. No. I started somewhere around 11:27:03
1990, but I'm not completely sure. 11:27:07
Q. And you left to go to Quest 11:27:10
Diagnostic? 11:27:20
A. Correct. 11:27:21
Q. Now, putting R.G.I. aside, did 11:27:26
you do any P.G.D. at Masonic Medical 11:27:30
Center? 11:27:34
A. How can you put R.G.I. aside? 11:27:34
That's where we did -- 11:27:38
Q. Putting R.G.I. aside for the 11:27:39
moment. 11:27:40
A. We were at Illinois Masonic, so 11:27:40
yes, we did P.G.D. at Illinois Masonic 11:27:43
Medical Center. 11:27:43
Q. Explain to me, then, the 11:27:47
relationship between Reproductive 11:27:48
Genetics Institute, R.G.I. and Illinois 11:27:51
Masonic Medical Center. 11:27:55
A. I really can't, because I 11:27:55

wasn't part of the management team, but 11:27:57
we were physically located in Masonic. 11:27:59
Whatever financial relationships that were 11:28:03
between the director of the Institute and 11:28:06
Illinois Masonic, I was not privy to, but I had 11:28:08
a single office for both functions and that's the 11:28:12
best I can do. 11:28:17
Q. In 2004, how much of your time 11:28:18
was spent -- I'm sorry, not 2004. We've 11:28:32
already established that. 11:28:35
When you left R.G.I. in 2000, 11:28:36
how much of your time was spent actively 11:28:42
involved in P.G.D.? 11:28:44
A. About 80 percent. 11:28:46
Q. I've asked you this, I guess; 11:28:48
you don't know the connection between 11:29:00
Illinois Masonic Medical Center and 11:29:01
R.G.I.? 11:29:06
A. You did ask me. 11:29:07
Q. And you do not know? 11:29:09
A. Correct. 11:29:11
Q. R.G.I. is not specifically 11:29:11
listed on your curriculum vitae. Why not? 11:29:14
A. Because it wasn't a salaried 11:29:16

position. 11:29:18
Q. During the entire time you were 11:29:18
at Masonic Medical Center, did R.G.I. exist and 11:29:23
did you work with them? 11:29:27
A. No. R.G.I. came into being 11:29:29
while I was there. The original program 11:29:32
chief there was an individual named Gene 11:29:36
Pergament and when Gene Pergament left 11:29:42
Illinois Masonic, Yury, Y-U-R-Y, Verlinsky, took 11:29:50
over and created the entity known as 11:29:59
Reproductive Genetics Institute. 11:30:01
Q. When? 11:30:01
A. Somewhere in the early '90s. 11:30:03
Excuse me, sometime in the early '90s. 11:30:07
Q. What were your responsibilities 11:30:10
in your volunteer position with R.G.I.? 11:30:14
A. I was the medical director. I 11:30:17
was responsible for all clinical services, 11:30:19
including genetic counselling. I was also the 11:30:21
director of the DNA diagnostic laboratory. 11:30:24
Q. Did you do -- well, you did 11:30:34
P.G.D. at R.G.I. What was your reason 11:30:37
for leaving R.G.I.? 11:30:40
A. Well, it was severalfold. Most 11:30:42

misdiagnosis due to allele dropout, then we began 11:44:50
to use it clinically and it's only when you use 11:44:56
it clinically that you really can develop the 11:44:58
data that shows you that you've improved 11:44:59
the situation. 11:45:03
Q. Once you -- I'm sorry. I 11:45:04
didn't mean to interrupt you. 11:45:06
A. That was the evolution of the 11:45:08
linked marker testing. Simultaneously, we did 11:45:10
studies to determine what the rates of 11:45:16
allele dropout were in various cells and 11:45:19
we looked at cultured fibroblasts, which 11:45:21
was the experimental technique we were 11:45:25
using. Some people in the literature 11:45:29
have used single lymphocytes. We never 11:45:30
used single lymphocytes to develop the 11:45:33
technology, but then also polar bodies 11:45:34
and blastomeres and what we discovered 11:45:38
was that the allele dropout rate in blastomeres 11:45:41
was much higher than in either single fibroblasts 11:45:43
and in literature single lymphocytes and 11:45:48
in polar bodies. In those other three 11:45:50
cell types, the allele dropout rate was 11:45:53
less than ten percent; but in blastomeres 11:45:56

we and others have found that the allele 11:45:58
dropout rate can be as high as twenty to 11:46:02
thirty percent. 11:46:06
So during that period of time 11:46:06
is when all these things coalesced and 11:46:08
then we have a series of publications 11:46:12
that are referenced in what you're saying. 11:46:17
The other issue in terms -- the 11:46:17
other issue we began reporting on this, I 11:46:27
believe, as early as 1996, '97 at the 11:46:30
International P.G.D. meetings and we 11:46:34
reported our results. Other people began 11:46:36
to try. 11:46:37
The other interesting 11:46:37
phenomenon is that obviously you need to 11:46:42
have a certain number of cases before you 11:46:44
can develop enough data and in the P.D.G. 11:46:47
centers that weren't doing as many cases 11:46:47
it took them perhaps to 2000, 2002, to 11:46:50
finally publish their results. 11:46:53
Q. So you will agree with me that 11:46:57
let's say you are aware that a lab in Europe is 11:46:57
doing multiplex P.C.R. testing. You can't just 11:47:01
based on that knowledge implement it in 11:47:07

your lab. You have to go through a tedious 11:47:10
time-consuming process to make sure that 11:47:13
it works in the setting of your lab with 11:47:16
the people that you're analyzing? 11:47:18
A. Well, once it's established in 11:47:20
literature and the primers have been 11:47:22
published and methods have been 11:47:22
published, it's a relatively straightforward 11:47:25
thing to implement if you have a lab 11:47:28
that's capable of doing preimplantation genetics 11:47:30
once the primers and the probes and the 11:47:32
conditions were published and we did 11:47:35
everything meticulously. We published 11:47:38
our materials and methods, showed people 11:47:38
how to do it, it should only have taken a 11:47:42
matter of months for another laboratory 11:47:44
to introduce the concepts. 11:47:47
Q. What is amplification -- let me 11:47:50
ask you this first. Did the development 11:47:55
of the use of genetics differ depending 11:47:57
on the disease or condition involved? 11:48:01
A. The general concept was the 11:48:03
same, but the linked markers were different. 11:48:06
Q. Is cystic fibrosis one of the 11:48:09

more different conditions to develop 11:48:20
linked markers for? 11:48:24
A. No. Actually, it's the 11:48:25
easiest. 11:48:28
Q. Why do you say that? 11:48:28
A. Because more was known about 11:48:29
the gene and its gene sequence. This was 11:48:31
prior to the completion of the human genome 11:48:36
project, so you had to have the sequences 11:48:40
available and cystic fibrosis was such a 11:48:42
well-studied gene that all these polymorphic 11:48:43
markers had been published. 11:48:46
Q. How many different mutations 11:48:46
are there of the cystic fibrosis gene? 11:48:49
A. There's over 1500 at the moment 11:48:51
that have been described associated with 11:48:54
cystic fibrosis. 11:48:57
Q. What is amplification in the 11:48:58
context in the use of genetic markers in 11:49:01
P.G.D.? 11:49:04
A. There's a technique known as 11:49:04
polymerase chain reaction. P-O-L-Y-M-E-R-A-S-E. 11:49:12
I'll never say the word again. From now on it's 11:49:17
P.C.R., which takes a sample of DNA and 11:49:21

something like surgery, which has been shown multiple times that a more experienced surgeon is a better surgeon, to laboratory testing, where if you have the appropriate quality controls in place, there's no reason why a small volume laboratory can't do a quality job. 11:53:39 11:53:41 11:53:43 11:53:46 11:53:49 11:53:54 11:53:56

Q. When you were at R.G.I., did you use gene chips or micro beads at that time? 11:53:59 11:54:17 11:54:22

A. No. 11:54:22

Q. Are you involved in any way indirectly with the use of gene chips or micro beads at the present time? 11:54:23 11:54:26 11:54:28

A. Yes. We run micro beads. 11:54:31

Q. When you did P.G.D. at R.G.I., was most of it for cystic fibrosis? 11:54:34 11:54:57

A. I don't know most of it. Certainly a decent percentage of it was. 11:55:00 11:55:03

Q. In how many instances would you say you've performed P.G.D. for cystic fibrosis? 11:55:14 11:55:19 11:55:24

A. Probably a couple of hundred. 11:55:24

Q. Over what period of time? 11:55:26

A. Over the eight-year span between 1992 and 2000. 11:55:28 11:55:32

Q. Do you know how many of the couples that were involved in that P.G.D. actually got pregnant? 11:55:34 11:55:40 11:55:44

A. Probably when I was there, we've had probably thirty births, I would guess. Thirty to forty births. 11:55:45 11:55:49 11:55:52

Q. Do you receive P.G.D. biopsy samples from clinics? 11:55:58 11:56:02

A. I told you, I don't do P.G.D. 11:56:03

Q. How many labs in the country currently do P.G.D.? 11:56:06 11:56:10

A. There's two kinds of P.G.D. there's P.G.D. by fluorescent in situ hybridization, which I won't say again, either. That's FISH. 11:56:11 11:56:13 11:56:13 11:56:25

Then there's P.G.D. for mendelian genetic disorders, which are done usually by P.C.R. 11:56:25 11:56:27 11:56:33

In terms of FISH laboratories, at the moment, I'm only aware of the Reproductive Genetics Institute, Mark Hughes and Genetics and I.V.F. Institute in Fairfax, 11:56:42 11:56:42 11:56:50 11:56:52

Virginia that's doing DNA-based preimplantation genetics. 11:56:55 11:56:59

FISH-based diagnosis is also Saint Barnabas in New Jersey with Santiago Munee, M-U-N-E-E, and I believe he has opened a satellite facility in southern California, also. 11:56:59 11:57:01 11:57:08 11:57:13 11:57:17

Q. So as far as you can tell, there are perhaps five labs today who are doing P.G.D.? 11:57:17 11:57:20 11:57:24

A. In the United States. 11:57:26

Q. In the United States, right. 11:57:26

A. Worldwide it's much larger. 11:57:30

Q. As of 2004, was it the same five labs, as far as you know? 11:57:32 11:57:35

A. Yes. 11:57:37

Q. Do you agree that the objective of P.G.D. is to lower the risk of a bad result from the naturally occurring 25 percent to a number approaching the impossible rate of zero? 11:57:38 11:57:45 11:57:49 11:57:54 11:57:57

A. Yes. 11:57:58

Q. Of the labs that are doing P.G.D., which ones are doing FISH now? 11:57:58 11:58:10

If you know? 11:58:13

A. I wouldn't. 11:58:14

Q. Do you know as of -- FISH wasn't done as of 2004, was it? 11:58:15 11:58:19

A. Oh, yes, it was. 11:58:21

Q. It was. Okay. 11:58:21

A. It was done in the '90s. 11:58:22

Q. What labs were doing FISH in 2004, if you know? 11:58:25 11:58:27

A. I don't know. Certainly Reproductive Genetics Institute was and Saint Barnabas in New Jersey was; but who else was doing it, I can't say. 11:58:28 11:58:32 11:58:33 11:58:36

Q. When you did P.G.D. in 2000, I guess was the last time you did it, what did your lab tell physicians and/or patients the failure rate was? 11:58:37 11:58:43 11:58:47 11:58:51

A. Failure or misdiagnosis? Please clarify. 11:58:53 11:58:56

Q. The misdiagnosis. 11:58:57

A. We told them it varied from case to case and embryo to embryo and each case was evaluated separately and we would tell people that at the time of transfer, 11:58:57 11:59:01 11:59:06 11:59:09

C. STROM, M.D., PhD.

A. Yes. 12:12:05
Q. Where? 12:12:05
A. Just colleagues in the same 12:12:05
field. We didn't work in the same lab. 12:12:07
Q. Did you and he ever work 12:12:09
together on a paper? 12:12:11
A. I don't think I did. I know 12:12:13
Yury did, Verlinsky. Or I think Yury did. I'm 12:12:17
under oath. 12:12:24
Q. Have you reviewed any other 12:12:27
cases, whether or not you offered an opinion, 12:12:35
involving Mark Hughes, either against him 12:12:37
or for him? 12:12:40
A. No. 12:12:42
MR. LEUCHTMAN: Off the record. 12:12:48
(Thereupon an off-the-record 12:13:01
discussion was held.) 12:13:01
MR. LEUCHTMAN: Back on the 12:13:01
record. 12:13:01
Q. Do you have in front of you -- 12:13:08
I think you do, you have the Genesis records, 12:13:09
correct? 12:13:13
A. Yes, I do. 12:13:13
Q. Would you look at the precase 12:13:14

C. STROM, M.D., PhD.

phone review of P.G.D. informed consent. 12:13:16
(The Witness perused the 12:13:27
exhibit.) 12:13:28
A. Sorry. I didn't need these in 12:13:28
2000 (Indicated). Yes. 12:13:35
Q. Now, were there any errors or 12:13:40
omissions in that protocol form that you have 12:13:49
found? 12:13:52
MR. STEIN: Do you mean 12:13:53
omissions against a standard? Is that 12:13:54
what you're referring to? 12:13:55
BY MR. LEUCHTMAN: 12:13:55
Q. Do you have an opinion whether 12:13:56
there were any errors or omissions in that form? 12:13:58
MR. STEIN: I object to the form 12:14:02
of the question. It's ambiguous. 12:14:04
MR. LEUCHTMAN: Okay. Swell. 12:14:07
You can answer the question. 12:14:09
(The Witness perused the 12:14:29
exhibit.) 12:14:30
MR. LEUCHTMAN: I promise you 12:14:30
sooner or later we'll talk about standards 12:14:32
and care. 12:14:35
MR. STEIN: When you say errors 12:14:35

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or omissions, are you talking about whether 12:14:38
there's an accurate transcription of what's 12:14:39
there or what was originally there or a typo? 12:14:42
MR. LEUCHTMAN: The minute the 12:14:46
Witness says he doesn't understand the 12:14:47
question, I'll be happy to rephrase it. 12:14:52
MR. STEIN: All right. 12:14:56
A. I don't see anything obvious. 12:15:26
MR. LEUCHTMAN: Okay. 12:15:43
BY MR. LEUCHTMAN: 12:15:47
Q. I'm jumping ahead of both of 12:15:49
us, I guess, to ask you this question, but you 12:15:53
say in the report that one of your criticisms are 12:15:56
that the Grossbaums should have been 12:16:01
advised by Dr. Hughes as to the nature of 12:16:04
allele dropout and as to polar body biopsy 12:16:08
and/or genetic marker testing, correct? 12:16:09
A. Yes. 12:16:12
Q. We'll get to that, but other 12:16:12
than that, did Dr. Hughes fail to advise 12:16:15
the Grossbaums of anything of which he 12:16:19
should have advised them, as far as you 12:16:21
can tell from his deposition, from his 12:16:23
records or from this precase phone review 12:16:25

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which memorializes his conversation, his 12:16:29
one and only conversation with them? 12:16:35
A. Other than those notable 12:16:37
exceptions. 12:16:39
Q. None? 12:16:40
A. None. 12:16:41
Q. So did Dr. Hughes advise the 12:16:41
Grossbaums of anything he should not have 12:16:44
advised them? 12:16:47
A. No. 12:16:48
Q. Now, we talked about the one 12:16:48
misdiagnosis. You are also a practicing 12:16:52
physician and have been ever since you 12:16:58
got your board certification in pediatrics, 12:17:00
correct? 12:17:04
A. Prior. 12:17:04
Q. If not before? 12:17:05
A. Yes. 12:17:06
Q. Have you ever been sued for 12:17:07
medical malpractice? 12:17:09
A. No. And you can look it up. 12:17:12
Q. I have and I didn't find 12:17:20
anything. In the context of this case, 12:17:22
how do you define standard of care? 12:17:24

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A. I define standard of care as what any reasonable P.G.D. laboratory would do at the time of the case. 12:17:27 12:17:30 12:17:36

Q. And do you limit that to the United States? 12:17:38 12:17:41

A. No. 12:17:41

Q. Why not? 12:17:42

A. I have no reason. 12:17:49

Q. And the time of the case, we agree, was 2004? 12:17:56 12:18:08

A. Uh-huh. Yes. 12:18:09

Q. Are you familiar with the standard of care in P.G.D. as of 2004? 12:18:10 12:18:15

A. Yes. 12:18:15

Q. What is the basis of that familiarity? 12:18:21 12:18:23

A. That I helped create the standard of care as of the year 2000 and I continued to be involved with the field by reading and speaking with practitioners in the field up until the present day. 12:18:24 12:18:27 12:18:31 12:18:34 12:18:38

MR. LEUCHTMAN: He needs to change the tape. 12:18:50 12:18:51

THE VIDEOGRAPHER: This marks 12:18:56

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the end of tape number one in the videotaped deposition of Dr. Charles Strom. We're going off the record. The time is 12:18. 12:18:57 12:19:01 12:19:04

(The deposition was suspended.) 12:19:12

THE VIDEOGRAPHER: This marks the beginning of tape number two in the videotaped deposition of Dr. Charles Strom. We're going on the record. The time is 12:28. 12:21:09 12:28:29 12:28:32 12:28:34 12:28:37

BY MR. LEUCHTMAN: 12:28:39

Q. Dr. Strom, do you agree that Mark Hughes never had a physician/patient relationship with the Grossbaums? 12:28:40 12:28:43 12:28:48

A. Yes. 12:28:48

Q. He's testified, in essence, that after the initial lengthy consultation he had with them in March of 2004, he does not believe he had a duty to counsel with them or communicate directly with them other than perhaps answering questions they might have had? Do you agree with that statement? 12:28:48 12:28:49 12:28:49 12:28:52 12:28:56 12:28:59 12:28:59 12:29:02

A. No. 12:29:02

Q. What is the basis of your 12:29:03

C. STROM, M.D., PhD.

disagreement? Or state what your disagreement is. 12:29:03 12:29:03

A. I believe whether him personally or someone from Genesis Genetics should have communicated to either the physician or to the Grossbaums the results of the amniocentesis and the uncertainties surrounding them. 12:29:07 12:29:09 12:29:12 12:29:13 12:29:17 12:29:21

Q. So the question as phrased your answer would be they didn't have a duty -- 12:29:23 12:29:25 12:29:27

A. I said they did have a duty. 12:29:27

Q. -- to communicate directly with the Grossbaums? 12:29:31 12:29:33

A. Correct. 12:29:37

Q. Do you agree that the I.V.F. physician or physicians are and should be the primary contact with a couple in an I.V.F. situation, even if it involves P.G.D.? 12:29:41 12:29:45 12:29:47 12:29:50

MR. HAMAD: Objection to form. 12:29:55

A. No. No, that I don't agree with. 12:29:55 12:29:57

Q. What's the basis of that disagreement? 12:29:57 12:29:59

C. STROM, M.D., PhD.

A. I don't believe in absolutes and I believe relationships are developed through specialists and consultants that can oftentimes -- I've met physicians that prefer that I do the communicating to them. 12:29:59 12:30:01 12:30:04 12:30:09 12:30:13 12:30:15

Q. Well, let me reread the question and I want you to pay attention to the word primary. Do you agree that the I.V.F. physicians are and should be the primary contact with the couple in an I.V.F. situation, even if it involves P.G.D.? 12:30:15 12:30:17 12:30:17 12:30:20 12:30:23 12:30:25

A. I don't think that's a question that's answerable. 12:30:29 12:30:30

Q. Do you agree that by having the I.V.F. physician or physicians being the primary contact with the couple in a P.G.D. situation, the risk of confusion or conflicting information is considerably reduced? 12:30:33 12:30:38 12:30:41 12:30:44 12:30:49

MR. HAMAD: Objection to form. 12:30:49

THE WITNESS: He objected. 12:31:01

MR. LEUCHTMAN: Great. 12:31:02

MR. HAMAD: I'm not your lawyer, so go ahead and answer. 12:31:03 12:31:06

what they felt the accuracy of the assay should be at the time and then at the time of analysis to communicate the fact that since there were so many failures that the risk of A.D.O. was very high in this case and that they should consider the transfer with a great deal of caution. 12:38:35 12:38:40 12:38:42 12:38:45 12:38:46 12:38:51 12:38:53

Q. Have you defined satisfactorily what genetic markers are in this deposition? 12:38:56 12:39:00

A. I believe I have. 12:39:05

Q. Now, in order to do testing with genetic markers, is it necessary to get DNA from family members other than the involved couple? 12:39:06 12:39:09 12:39:12 12:39:16

A. Yes. 12:39:17

Q. In 2004, was that DNA provided in the form of blood? 12:39:18 12:39:20

A. No. 12:39:22

Q. How else were you getting DNA in 2004? 12:39:23 12:39:27

A. I thought you said provided in this case. 12:39:28 12:39:30

Q. No, I said in 2004, was DNA provided when used for genetic markers in 12:39:30 12:39:34

the form of blood? 12:39:37

A. It was either in blood or skin biopsies. Yes. 12:39:39 12:39:42

Q. I'd like you to turn to page three of the precase phone review of P.G.D. informed consent. 12:39:43 12:39:53 12:39:59

(The Witness perused the exhibit.) 12:40:04 12:40:14

A. Uh-huh. 12:40:14

Q. Where it says -- and I'll find the line for you, if I can. 12:40:15 12:40:17

"? Blood possible from parents? Seems not." 12:40:22 12:40:27

Do you see that? 12:40:28

A. Um-hmm. 12:40:29

Q. Now, does that suggest to you that for whatever reasons, the Grossbaums were not willing to provide Genesis with DNA by way of blood from other family members? 12:40:29 12:40:31 12:40:35 12:40:37

A. Not at all. 12:40:37

Q. Well, how do you interpret that? 12:40:38

A. It means they asked -- we call the parents the Grossbaums. So my guess would be that he asked the Grossbaums for 12:40:40 12:40:42 12:40:46

their own blood. 12:40:48

Q. You interpret that as meaning their blood, not their parents' blood? 12:40:49 12:40:53

A. Right. We would call their parents grandparents and siblings, but Mark Hughes may have a different interpretation, I don't know; but the appropriate request is not just for grandparents, but for siblings. 12:40:53 12:40:56 12:41:04 12:41:06 12:41:08

Q. If you know, and I've asked you this in another form -- 12:41:13 12:41:28

A. That was page four, by the way. 12:41:29

Q. Pardon me? 12:41:29

A. That was on page four. Just a correction. 12:41:32 12:41:32

Q. No, it isn't. 12:41:32

A. Yes, it is. My page four. 12:41:36

MR. HAMAD: The bottom of page four -- 12:41:37 12:41:38

THE WITNESS: No, the middle of page four. I see it's page three up top. Okay, it's confusing. Go ahead. 12:41:39 12:41:41 12:41:46

MR. LEUCHTMAN: Okay. 12:41:48

BY MR. LEUCHTMAN: 12:41:49

Q. Now, I've asked you this in one 12:41:53

form or another and -- but I'll ask again. Do you know how many labs in the United States used genetic markers at all in early to mid 2004 for P.G.D.? 12:41:56 12:42:01 12:42:02 12:42:05

A. I know of one for sure. That was my laboratory. 12:42:08 12:42:12

Q. And you were not specifically aware of any other lab at that time doing that? 12:42:13 12:42:14

A. No. 12:42:17

Q. Correct? 12:42:18

A. Correct. 12:42:18

Q. Did your lab use genetic markers for two mutations at that time? 12:42:19 12:42:25

A. No. We used genetic markers for three linked markers and whatever mutations the patients had. We always looked at the specific mutations in addition to the three linked markers. So in this case, we would have looked at five. 12:42:27 12:42:31 12:42:34 12:42:37 12:42:39 12:42:44

Q. And you personally started doing P.G.D. in either 1990 or the early '90s? 12:42:46 12:42:48 12:42:52

A. Yes. 12:42:53

Q. When did you first read about 12:42:53

although this isn't a de benne esse deposition anyway, because what is done internationally is not standard of care; but that aside, let me -- 13:08:48 13:08:52 13:08:55 13:08:58

MR. STEIN: That's your statement. 13:08:58 13:08:58

MR. LEUCHTMAN: Pardon me? 13:08:59

MR. STEIN: That's -- you're making a legal statement now for the Witness? 13:08:59 13:09:00 13:09:02

MR. LEUCHTMAN: I'm -- for the Witness? No. It's for the record. 13:09:03 13:09:06

MR. STEIN: Oh, I see. 13:09:08

BY MR. LEUCHTMAN: 13:09:08

Q. Putting aside allele dropout and issues of multiplex testing polar body biopsy, do you agree that in other respects Dr. Hughes adequately explained the process of P.G.D. to the Grossbaums? 13:09:12 13:09:14 13:09:16 13:09:19 13:09:21

A. Yes, with those exceptions. 13:09:24

Q. If Dr. Hughes had attempted to explain allele dropout to the Grossbaums in his one-hour plus conversation with them, do you think they would have understood what 13:09:26 13:09:33 13:09:35 13:09:41

he was talking about? 13:09:44

A. I think it's possible to put things in layman's terms, yes. 13:09:45 13:09:49

Q. Not having read the depositions of the Grossbaums, do you have any idea of the level of their sophistication or lack of the same in issues such as this? 13:09:51 13:10:02 13:10:03 13:10:09

A. No. 13:10:11

Q. Can you say, without engaging in speculation, guess or conjecture, that if Dr. Hughes had explained A.D.O. to the Grossbaums, it would have been made a difference in their decision to go forward with P.G.D.? 13:10:11 13:10:23 13:10:23 13:10:27 13:10:28

A. No. 13:10:31

Q. Do you know whether in early to mid 2004, the average P.G.D. provider in the United States with reasonable skill and care specifically advised couples consulting with them as to the nature of allele dropout? 13:10:34 13:10:39 13:10:43 13:10:45 13:10:50

A. Yes. 13:10:52

Q. How are you aware of that knowledge? 13:10:52 13:10:55

A. Because it's what we were doing and what the people that we were talking 13:10:55 13:10:59

to at meetings were doing. There are I.V.F. providers who use genetics consultation and any reasonable P.G.D. provider would have had that discussion at that time. 13:11:01 13:11:05 13:11:11 13:11:15

Q. When you say what we were doing, you mean R.G.I. in Chicago? 13:11:16 13:11:18

A. Yes. And the greater P.G.D. community. 13:11:20 13:11:24

Q. Did any of the following labs advise couples consulting with them as to the nature of allele dropout: R.G.I. in Chicago, you said yes. 13:11:25 13:11:27 13:11:31 13:11:32

A. Yes. 13:11:33

Q. Reprogenetics in New Jersey? 13:11:33

A. I can't say what they were doing. 13:11:37 13:11:37

Q. Genetics and I.V.F. in Virginia? 13:11:39 13:11:42

A. Can't say what they were doing. 13:11:42

Q. And Cornell Medical Center in New York City? 13:11:43 13:11:46

A. Can't say what they were doing. 13:11:46

Q. Please describe what polar body biopsies are? Let me back up. 13:11:47 13:11:52

Are you aware of any other P.G.D. labs that existed in early to mid 2004 besides the four that I've mentioned? 13:11:54 13:11:58 13:12:03

A. There was another lab called Shady Grove that I don't know if they were doing DNA-based diagnoses at the time. Baylor had a small program they were trying to develop. There was a lab in Florida that was trying to develop P.G.D., but I'm not sure what they were doing. 13:12:05 13:12:08 13:12:09 13:12:12 13:12:16 13:12:20 13:12:23 13:12:23

Q. Where was Shady Grove? 13:12:27

A. I think it's in North Carolina. LabCorp bought it. 13:12:27 13:12:30

Q. And you think they were in existence in 2004, but you're not sure? 13:12:31 13:12:34

A. I don't know. 13:12:36

Q. You don't know. Okay. And, of course, you also don't know what they were advising couples? 13:12:37 13:12:37 13:12:39

A. No, because I wasn't sitting in the room with them. 13:12:41 13:12:44

Q. Right. And you don't know what Baylor was? 13:12:44 13:12:47

option of polar body removal in P.G.D. cases in cystic fibrosis in 2004? 13:16:25 13:16:31

A. I don't know the statistics. I simply don't know. 13:16:32 13:16:35

Q. Do you agree that it's true that polar body biopsies or removal are mainly done because a particular hospital or country does not permit biopsies of embryos? 13:16:37 13:16:45 13:16:50 13:16:53 13:16:57

A. I don't think that's an accurate statement. 13:16:58 13:17:00

Q. What foreign countries do polar body removal regularly? 13:17:00 13:17:02

A. Germany, France, Belgium, Italy. 13:17:02 13:17:06

Q. Is that because of restrictive laws? 13:17:08 13:17:10

A. I'm not told. I don't know why they do polar body biopsies. There are restrictive laws in this country. 13:17:10 13:17:13 13:17:16

Q. Do you agree that even today polar body biopsy is not a mainstream approach in the United States? 13:17:16 13:17:18 13:17:20

A. I disagree. 13:17:21

Q. What is the basis of your opinion to disagree with that? 13:17:22 13:17:26

A. By the sheer numbers that we still continue to do in the lab in Chicago. We provide services to I.V.F. providers all over the United States and it's just one of the many -- it's an established option. 13:17:28 13:17:32 13:17:35 13:17:39 13:17:41

Q. And your definition of mainstream is whether something is established? 13:17:46 13:17:53

A. I said it's established. I don't know the definition of mainstream. 13:17:55 13:17:57

Q. How is it that you're aware of what R.G.I. in Chicago practices are today? 13:18:01 13:18:04

A. Because I recently went to Yury Verlinsky's funeral in October -- in July or August and I spent a great -- a day or two with them reviewing what they're doing, finding out what's going on. 13:18:07 13:18:13 13:18:14 13:18:17 13:18:20

Q. Do you know whether in 2010 the average P.G.D. provider in the United States with reasonable skill and care would have been used genetic marker testing for cystic fibrosis in undergoing P.G.D.? 13:18:21 13:18:23 13:18:27 13:18:29 13:18:34

MR. STEIN: Object to the form 13:18:37

of the question. The doctor already said he doesn't know what average means in the terms of the context. 13:18:38 13:18:41 13:18:43

BY MR. LEUCHTMAN: 13:18:46

Q. We're going to define average as meaning that more of them are doing a certain thing or engaged in a certain practice than not. Using that definition, and that's going to be the consistent definition for my questions for averaging. 13:18:46 13:18:48 13:18:53 13:18:57 13:19:00 13:19:04

A. I would say the overwhelming majority of P.G.D. centers would offer linked marker testing for patients that are compound heterozygotes. 13:19:05 13:19:07 13:19:09 13:19:16

Q. Using my definition of average, do you know whether in early to mid 2004, the average P.G.D. provider in the United States with reasonable skill and care would have used genetic marker testing for cystic fibrosis in undergoing preimplantation genetic diagnosis? 13:19:21 13:19:52 13:19:56 13:19:58 13:20:01 13:20:05

MR. STEIN: I object to the form of the question. 13:20:10 13:20:11

A. As I said, the overwhelming majority of centers with a case of cystic 13:20:11 13:20:14

fibrosis with parents of compound heterozygosity would offer linked marker testing. 13:20:18 13:20:22 13:20:24

Q. In 2004? 13:20:24

A. Yes. 13:20:25

Q. What's the basis of that opinion? 13:20:25 13:20:27

A. Basis of that opinion is the overwhelming literature in support of this, my attending meetings and speaking with people at the meetings in terms of what they were providing in their own practice and the fact that we were providing probably over half the services for P.G.D. in the country at that time. 13:20:27 13:20:29 13:20:34 13:20:36 13:20:39 13:20:40 13:20:42 13:20:45

Q. R.G.I. was? 13:20:46

A. Uh-huh. 13:20:48

MR. STEIN: Yes? 13:20:50

THE WITNESS: Yes. 13:20:52

BY MR. LEUCHTMAN: 13:20:54

Q. As of early to mid 2004, without guessing or making assumptions, which of the following labs were doing genetic marker testing for cystic fibrosis: R.G.I. in Chicago? 13:20:55 13:20:57 13:20:57 13:21:01

A. Yes. 13:21:06
Q. Reprogenetics in New Jersey? 13:21:06
A. Don't know. 13:21:11
Q. Genetics and I.V.F. in 13:21:12
Virginia? 13:21:12
A. Don't know. 13:21:12
Q. Cornell Medical Center in New 13:21:14
York City? 13:21:16
A. Don't know. 13:21:16
Q. Genesis Genetics? 13:21:17
A. Don't know. Oh, no. Genesis 13:21:18
wasn't. He said he wasn't. 13:21:22
Q. Shady Grove? 13:21:22
A. No. 13:21:24
Q. No, you don't know; or no, they 13:21:24
weren't? 13:21:24
A. No, I don't know. 13:21:27
Q. Baylor? 13:21:28
A. Don't know. 13:21:29
Q. And the lab in Florida we 13:21:32
talked about? 13:21:40
A. Don't know. 13:21:41
Q. Do you agree with Drs. Kangpu 13:21:42
Xu and Mark Hughes that under the circumstances 13:21:50

existing at the time in this case it was proper 13:21:52
to recommend embryos seven and eight for 13:21:54
transfer? 13:21:58
A. No. 13:21:58
Q. What should have been done, 13:22:01
given -- you've seen the analysis of the embryos, 13:22:07
correct? 13:22:11
A. Yes. 13:22:11
Q. All right. What recommendations, 13:22:13
if any, should Dr. Hughes have made at that 13:22:15
time? 13:22:19
A. He should have had the 13:22:19
conversation either with the physician or 13:22:20
with the Grossbaums saying that given the 13:22:22
details of this case, that these diagnoses could 13:22:24
not be considered reliable in that the Grossbaums 13:22:28
should make the decision based on that data. 13:22:34
Q. So you do not believe that any 13:22:49
different embryos should have been transferred? 13:23:02
A. No. 13:23:05
Q. Do you believe the procedure 13:23:06
should have been cancelled or postponed 13:23:10
or is it just your testimony that was up to the 13:23:12
Grossbaums? 13:23:15

A. Correct. 13:23:16
Q. Do you have an opinion as to 13:23:17
what they would have agreed or not agreed 13:23:22
to do? 13:23:25
A. No opinion. 13:23:27
Q. Do you agree that the two 13:23:28
embryos Dr. Hughes said were okay for 13:23:42
transfer were eight and ten? 13:23:45
A. That's what I was told. 13:23:47
Q. Well, you have it in front of 13:23:48
you. 13:23:50
A. I was told that those were the 13:23:53
ones that were transferred. 13:23:55
MR. STEIN: Look at the report. 13:23:57
THE WITNESS: I'm sorry. You 13:23:59
took something from me. Oh, here. 13:24:05
(The Witness perused the 13:24:11
exhibit.) 13:24:12
A. Well, in this particular report, 13:24:12
embryos four, seven, eight, thirteen and 13:24:24
fifteen would be considered eligible for 13:24:31
transfer. 13:24:35
Q. On the right-hand column, do 13:24:36
you agree that the two that Dr. Hughes or 13:24:40

his lab said okay for transfer were seven 13:24:44
and eight? 13:24:47
MR. HAMAD: Objection to form, 13:24:48
asked and answered. 13:24:49
A. That's actually incorrect. The 13:24:50
two that he's got are ten -- 13:24:52
Q. I'm sorry, I meant eight and 13:24:54
ten. I apologize. Seven and eight were 13:24:56
transferred and do we agree that the two 13:24:59
he said were okay for transfer were eight 13:25:01
and ten? 13:25:04
MR. HAMAD: Objection to form. 13:25:05
Asked and answered. He already said 13:25:07
which ones were eligible for transfer; but 13:25:07
beyond that, you can answer it again. 13:25:08
A. I think what's interesting to 13:25:10
me is that he's got several that say carrier at 13:25:14
worst. 13:25:18
Q. No, I didn't ask what interests 13:25:19
you. I asked you do you agree that the two 13:25:21
embryos that are said in that report to be okay 13:25:24
for transfer are eight and ten? 13:25:29
A. Yes. 13:25:32
Q. All right. Do you agree that 13:25:33

other than control samples CG and MG, the only cells that were biopsied that had no deletion on the paternal side were samples two, which had a mutant maternal allele and therefore possible paternal A.D.O., eight and ten? 13:25:36 13:25:40 13:25:44 13:25:47 13:25:51 13:25:57

MR. HAMAD: I have an objection to this line of question, in that you stopped him from answering the question, the prior question, and also in the fact that I think you're asking the question -- 13:25:58 13:26:01 13:26:04 13:26:06 13:26:08

MR. LEUCHTMAN: No, I didn't stop him from answering the question. 13:26:09 13:26:10

MR. HAMAD: He wasn't finished. 13:26:11

MR. LEUCHTMAN: I encouraged him to answer the question and not to ramble on. 13:26:13 13:26:14

MR. STEIN: I object to the characterization of the Doctor rambling on. He's responding to your questions. 13:26:19 13:26:23 13:26:25

MR. LEUCHTMAN: Once encouraged, yes, I agree, and I'd like an answer to this one. 13:26:26 13:26:28 13:26:29

A. Okay. Column two, no deletion, sample number two; no deletion, sample 13:26:29 13:26:33

number eight; no deletion sample number ten. 13:26:35 13:26:38

Q. What does no deletion mean? 13:26:38

A. It means, the Delta F 508 mutation was not observed in those samples. 13:26:40 13:26:46

Q. What does no amp mean? 13:26:50

A. No amp means no amplification. Means no analysis. 13:26:53 13:26:57

Q. Doctor, I'm going to ask you questions about two embryos, eight and ten and I want to make it clear it that I'm not asking whether one was more likely than the other, but whether you can say without engaging in guess, speculation, or conjecture that either one in and of itself was more likely than not the involved embryo. Do you follow me? 13:26:58 13:27:00 13:27:02 13:27:06 13:27:08 13:27:10 13:27:12 13:27:14 13:27:18

A. No. That's a stupid question. 13:27:19

There are higher risks to one of these embryos than the other embryo, but that doesn't mean it's more likely than not to have been the one that caused the pregnancy. 13:27:22 13:27:25 13:27:28 13:27:32 13:27:34

Q. That's what I'm trying to ask 13:27:34

you now. 13:27:36

A. There's no way to know which of those embryos resulted in the pregnancy. 13:27:36 13:27:39

Q. There's no way to know. 13:27:41

A. No. 13:27:44

Q. All right. Do you have an opinion as to the percentage chances of -- strike that. 13:27:49 13:28:44 13:28:48

Now, this is an issue we touched on earlier. Was it reasonable for Dr. Hughes to set as a condition to Genesis doing P.G.D. the undergoing by a couple of C.V.S. or amniocentesis? 13:28:51 13:28:58 13:29:01 13:29:05 13:29:08

A. A requirement? I don't think that's reasonable. 13:29:14 13:29:16

Q. As a precondition of his getting involved. 13:29:17 13:29:18

A. Well, that's up to him. It's his decision. 13:29:19 13:29:22

Q. Do you agree or disagree that it's important scientifically for a lab doing single cell P.G.D. to learn that there's been a failure or a misdiagnosis ten to fifteen weeks into a pregnancy as opposed 13:29:23 13:29:25 13:29:29 13:29:34 13:29:37

to after the baby has been born? 13:29:41

A. No. 13:29:43

Q. Do you agree that as of early to mid 2004, Genesis consisted of scientists trying to develop a complicated single cell test? 13:29:44 13:29:49 13:29:52

MR. STEIN: I object to the form of the question. How is he supposed to know what was going on at Genesis Genetics? 13:29:58 13:29:59 13:30:02 13:30:04

MR. LEUCHTMAN: I guess especially now that he's coached, he can say I don't know. 13:30:04 13:30:07 13:30:10

MR. STEIN: You know, when you ask a question that is loaded with presumptions and assumptions that on its face is beyond the canon of anything who's not intimately involved in the operation of Genesis Genetics, the question speaks for itself as being inappropriate and if you couch it in those terms, you get an objection from me. 13:30:10 13:30:11 13:30:14 13:30:16 13:30:22 13:30:26 13:30:27 13:30:30 13:30:33 13:30:37

MR. LEUCHTMAN: Noted. 13:30:37

MR. STEIN: Thank you. 13:30:38

weeks into the pregnancy other than amnio or C.V.S.? 13:35:57 13:35:58
A. We can't do an amnio that early. Other than prenatal diagnosis. 13:35:59 13:36:06
Q. Ten to sixteen weeks. 13:36:06
A. We can't do an amnio at 10 to 16 weeks. 13:36:06 13:36:06
Q. When do you do an amnio? 13:36:06
A. From 16 weeks up. C.V.S. is early. 13:36:06 13:36:09
Q. All right. Well, I thought I said 16 weeks, and you're saying -- 13:36:10 13:36:13
A. You said 10 to 16 weeks. 13:36:15
Q. Okay. 13:36:18
A. Well, you're trying to perjure me, I'm sure. 13:36:18 13:36:23
Q. I'm trying to what? 13:36:23
A. I'm trying to be accurate. You can do a C.V.S. at any time after nine weeks; and yes, the only way to determine whether the child is afflicted with cystic fibrosis is to do a prenatal diagnosis. 13:36:23 13:36:28 13:36:28 13:36:30 13:36:33
Q. And as of 2004, were those prenatal diagnostic procedures C.V.S. or 13:36:33 13:36:36

amniocentesis? 13:36:39
A. Correct. 13:36:41
Q. And the range for C.V.S., so that we're agreed you're not being tricked, either attempted or otherwise, or to use your word coerced, the range for C.V.S. is what? 13:36:42 13:36:46 13:36:51 13:36:53 13:36:56
A. Nine weeks to twelve weeks, usually. 13:36:56 13:36:59
Q. For amnio? 13:36:59
A. Sixteen weeks and up. 13:37:02
Q. And just so that we're clear, do you agree that the Grossbaums agreed in writing with Dr. Hughes, Genesis Genetics and N.Y.U. that Chaya Grossbaum would undergo C.V.S. or amniocenteses if she got pregnant in the course of this P.G.D., I.V.F. endeavor? 13:37:06 13:37:11 13:37:13 13:37:15 13:37:20 13:37:20 13:37:26
A. Actually, I don't know that. 13:37:26
Q. Do you have the N.Y.U. records? 13:37:27
A. No. 13:37:30
Q. Wow. You are a scientist, right? 13:37:31 13:37:38
A. I consider myself to be. 13:37:38

Q. All right. 13:37:40
A. A medical scientist. 13:37:42
Q. And a scientist wants to look at the universe of relevant information available to him or her in order to formulate opinions based upon that body of knowledge, correct? 13:37:43 13:37:47 13:37:52 13:37:56
A. Yes. 13:38:01
Q. When you were looking at the P.G.D. I.V.F. process -- 13:38:02 13:38:04
MR. HAMAD: Objection to form. 13:38:08
BY MR. LEUCHTMAN: 13:38:09
Q. Were you not, in -- 13:38:09
MR. LEUCHTMAN: I'm sorry, what's the problem with the question, Jay? How is that incorrect as to form? 13:38:11 13:38:12 13:38:15
MR. HAMAD: Well, you're telling him what he was looking at. That's what he was asked to do. You're telling him looking at the P.G.D. I.V.F. process, he wasn't asked to look at that. 13:38:16 13:38:18 13:38:18 13:38:22 13:38:23
MR. LEUCHTMAN: You're saying I can't lead an opposing expert? 13:38:24 13:38:26
MR. STEIN: You can, but you can't expand by virtue of your question the 13:38:29 13:38:30

scope of the Witness's investigation. If he was asked to look at Genesis Genetics' participation in this process, then that's what he was asked to look at. 13:38:35 13:38:39 13:38:43 13:38:43
Why don't you find out whether he was asked to evaluate N.Y.U.? 13:38:43 13:38:45
MR. LEUCHTMAN: Well, I know he wasn't asked to evaluate very much, because he didn't get your clients' deposition transcripts, any of the transcripts from N.Y.U. or N.Y.U.'s records, which frankly strikes me as -- and I'm not even sure of the use of the word intellectually, but I'm going to say it, intellectually dishonest. How's that? 13:38:47 13:38:48 13:38:48 13:38:52 13:38:54 13:38:58 13:39:01 13:39:06 13:39:07
MR. STEIN: You can use the term, but there are some of us who recognize that there's a dichotomy of specialty and interest in terms of the physicians who are involved in I.V.F. and the physicians who were involved in genetic analysis; and therefore, maybe the doctor was just asked, as I indicate to you he was, to report on what the 13:39:07 13:39:09 13:39:11 13:39:14 13:39:16 13:39:18 13:39:20 13:39:25 13:39:28

conduct of Genesis Genetics was in this process of P.G.D. 13:39:32 13:39:33

So let's not begin to start playing games in the litigation field. Lawyers can ask questions, like you have been asking, that may go far beyond the scope of the Witness's involvement in this case. 13:39:36 13:39:40 13:39:43 13:39:45 13:39:50

BY MR. LEUCHTMAN: 13:39:56

Q. Doctor, are you familiar with the story about the four or five blind people being taken up to an elephant and one of them thinks it's a snake, because he gets the trunk to handle and another one thinks it's maybe a tree because he's got his arms around a leg -- 13:39:57 13:39:58 13:40:02 13:40:07 13:40:10 13:40:13 13:40:14

A. I'm familiar with the story. 13:40:14

Q. Were you satisfied as a scientist in your role at only finding the snake and ignoring the larger picture of what was going on with the Grossbaums in the P.G.D. I.V.F. endeavor that resulted in the birth of Rosie Grossbaum? 13:40:16 13:40:18 13:40:22 13:40:26 13:40:29 13:40:33

MR. HAMAD: Object to form. 13:40:37

A. I was asked to do a task. I reviewed the materials I was sent and I did my task. 13:40:38 13:40:38 13:40:42

This is not a scientific endeavor, this is a legal endeavor and in my experience, they're mutually exclusive. 13:40:42 13:40:46 13:40:49

Q. In my experience in this deposition, they are, but that's not the point we're getting at. 13:40:55 13:40:57 13:40:57

A. Are you insulting me personally? I just want to know. 13:40:59 13:41:02

Q. I don't know you, but what I am insulting is that you can make assessments that affect someone's reputation and livelihood without looking at the entire picture, just looking at one corner of a page that constitutes the universe of available facts in this case. 13:41:03 13:41:06 13:41:10 13:41:14 13:41:16 13:41:19

A. Counselor, whether or not this patient would have had a C.V.S. or a termination is irrelevant to the conduct of the case. 13:41:21 13:41:23 13:41:27

Q. I'm not just talking about that. 13:41:30

MR. HAMAD: I object to this whole line of questioning and I dare to call it questioning. It's more a barrage of the Witness and back and forth here. 13:41:30 13:41:32 13:41:32 13:41:34

Listen. Here's the bottom line. He was asked to do something, he reviewed what he reviewed, he gave an opinion. That's it. Now trying to expand the scope of this Witness here is not proper, okay? 13:41:36 13:41:37 13:41:39 13:41:40 13:41:42 13:41:44

MR. LEUCHTMAN: I'm not trying to get him to testify against your client, Jay, and I appreciate that you are otherwise somehow -- well, I'm not sure what incites your passion in this line of questioning. 13:41:46 13:41:47 13:41:47 13:41:51 13:41:54 13:41:56

MR. HAMAD: Well, if you have thirty seconds, I could explain it to you exactly, because, I mean -- 13:42:00 13:42:01 13:42:04

THE WITNESS: You guys only have 17 minutes to your conference call. 13:42:05 13:42:07

MR. HAMAD: Then I guess not. 13:42:13

BY MR. LEUCHTMAN: 13:42:28

Q. Well, it's your opinion that there's nothing in Dr. Hughes's records, the contractual agreement to have I.V.F. -- not I.V.F. -- the contractual agreement 13:42:28 13:42:30 13:42:37 13:42:37

to have C.V.S. or amnio aside and this Evans reference aside, that indicates that there was a discussion between Dr. Hughes and the Grossbaums about amnio or C.V.S. or that reflected their attitude about it one or the other, correct? 13:42:42 13:42:45 13:42:49 13:42:54 13:42:59 13:43:05

A. Correct. 13:43:07

Q. And might the N.Y.U. records shed some light on the attitude of the Grossbaums about C.V.S. or amnio? 13:43:07 13:43:09 13:43:11

MR. STEIN: That's speculation. You told him not to speculate. 13:43:17 13:43:19

MR. LEUCHTMAN: Well, it is now. Had he had the records, it wouldn't be. 13:43:19 13:43:20

A. You asked me not to speculate and I won't. 13:43:23 13:43:25

Q. Well, you've made a statement that they were coerced into having amnio or C.V.S., although now you've been informed that they didn't have it. All right. The long and short of it is you don't know what the N.Y.U. records say on that issue. 13:43:30 13:43:34 13:43:41 13:43:48 13:43:49 13:43:53

A. That's right. 13:43:56

Q. Or since you say it's a couple's 13:43:56

C. STROM, M.D., PhD.
you. 13:57:09
BY MR. LEUCHTMAN: 13:57:10
Q. Sir? 13:57:10
A. Why don't you read them back to me. You read them to me before. 13:57:10 13:57:17
Q. Read what to you? 13:57:19
A. My conclusions. That's what you're asking, isn't it? 13:57:21 13:57:24
Q. Well, okay. Your conclusions had to do with certain things that Dr. Hughes, in your opinion, either did that he shouldn't have done or didn't do that he should have. 13:57:26 13:57:29 13:57:34 13:57:37
A. That's correct. 13:57:41
Q. I'm asking now is there a causal link between that list of five or six opinions and the bad result in that case? 13:57:42 13:57:44 13:57:46
MR. STEIN: He's asked and answered that question. 13:57:49 13:57:50
A. Well, causal is, I mean, it's contributory. 13:57:54 13:58:00
Q. What does that mean? 13:58:01
A. It contributed to the outcome of this case. 13:58:02 13:58:06
Q. Explain in what way you believe 13:58:07

C. STROM, M.D., PhD.
it contributed. 13:58:12
A. Well, in several ways. First the case shouldn't have been done to begin with in this manner. Second, the fact that it was done and done poorly matters; and third, that it ended up with the birth of an affected child and I think that they all contribute. 13:58:13 13:58:15 13:58:18 13:58:22 13:58:25 13:58:28 13:58:31
Q. Can each of the following things be possible causes of failure or misdiagnosis in P.G.D.? One: Mosaicism? 13:58:34 13:58:37 13:58:41
A. Yes. 13:58:45
Q. Quickly, what is mosaicism? 13:58:45
A. Mosaicism is when every cell in the embryo is not identical. 13:58:48 13:58:51
Q. As of 2004, was it possible to predict mosaicism with any degree of medical probability? 13:58:53 13:58:56 13:59:00
A. No. 13:59:01
Q. Was mosaicism a possible, not necessarily a probable or the probable, but a possible cause of the failure or misdiagnosis in this case? 13:59:02 13:59:07 13:59:10 13:59:11
A. It could be ruled out by 13:59:11

C. STROM, M.D., PhD.
testing of the child, but I don't think that that testing has been done yet. So at the moment, it's still possible. 13:59:14 13:59:18 13:59:21
Q. So with that in mind -- I don't want to make any assumptions about what you might say -- can you without speculating ascribe a percentage of the possible causes of the bad result in this case to mosaicism? 13:59:24 13:59:36 13:59:39 13:59:42 13:59:46
A. Negligibly small. 13:59:49
Q. How did DNA contamination occur, or how can it occur, particularly six years ago in 2004? 14:00:00 14:00:04 14:00:09
A. Well, DNA contamination can occur, I don't know if intracytoplasmic sperm injection was done in this case. I assume it was, because that was the standard of care. Then DNA contamination can occur if the needle as it's going in brushes against coronal cells that surround the embryo. 14:00:10 14:00:13 14:00:23 14:00:26 14:00:29 14:00:33 14:00:37 14:00:41
Q. Can ambient DNA contaminate an embryo from, first, the embryologist during fertilization? 14:00:45 14:00:49 14:01:02
A. Theoretically, yes. We've 14:01:02

C. STROM, M.D., PhD.
never observed it. Embryologists wear gloves. 14:01:02 14:01:03
Q. Second, the way the egg is fertilized? 14:01:03 14:01:06
A. Yes. That's I-C-S-I. ICSI. It's the abbreviation for intracytoplasmic sperm injection. 14:01:06 14:01:06 14:01:17
MR. LEUCHTMAN: It's two o'clock. 14:01:17 14:01:19
MR. HAMAD: My office is calling in with the Judge and everybody on the line. 14:01:20 14:01:22 14:01:25
MR. LEUCHTMAN: All right. 14:01:26
BY MR. LEUCHTMAN: 14:01:26
Q. Can ambient DNA contaminate an embryo from cells near the egg when it was removed from the ovary? 14:01:27 14:01:30 14:01:34
A. I just said that. 14:01:35
Q. Okay. And from cells attaching to the person, such as from the prostate? 14:01:36 14:01:39
A. I have not heard of that one, but I guess it's a possibility. 14:01:42 14:01:46
Q. Was DNA contamination a possible cause of the failure or misdiagnosis in 14:01:49 14:01:51

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
IN THE DISTRICT OF NEW JERSEY
----------/
CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually, and as Guardian ad litem of the Infant, ROSIE GROSSBAUM,
Plaintiffs,
-vs- Index No. 07-CV-359
GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE, and NEW YORK UNIVERSITY HOSPITALS CENTER, both Corporations of the State of New York, ABC CORPORATIONS: 1-10 and John Doe,
Defendants.
_____/

PAGE 1 - 82

The Deposition of DR. MARK HUGHES,
Taken at 1380 Trowbridge Place,
Detroit, Michigan,
Commencing at 12:55 p.m.,

MR. STEIN: Okay.

MR. LEUCHTMAN: I'm not telling him not to answer.

THE WITNESS: Oh. I'm now gun shy. Whenever you talk I don't know what to say.

Yes, there was. I was -- can I extrapolate? I was recruited to the NIH and Georgetown University because of my research in embryo science, and did significant amounts of work there, and gave major lectures at the NIH and at Georgetown, and taught on the subject, and was quite publicly known. Then there was a change in the administration of Washington. The republicans took the house for the first time in decades, and Newt Gingrich was the speaker of the house, and the philosophy of doing anything whatsoever with an embryo anywhere near the NIH became of a concern because we were all very actively trying to double the NIH budget at the time. So we were all busy lobbying to get more money for biomedical research. And so suddenly I became a liability in that quest.

BY MR. STEIN:

Q. And so they asked you to leave?

A. Yes. Well, they said I could stay, but I couldn't work on this. And then the good Jesuits were now in the public eye, and they became concerned because it was

They do sickle cell anemia and cystic fibrosis, and there's a few tests that they do there inhouse, but most of the cases they send to us. So it's counting apples and oranges, because they're different techniques. One technique is looking at genes, and one technique is counting chromosomes to look for abnormal number of chromosomes.

Q. So they don't do single-cell analysis for cystic fibrosis there?

A. They do. They do cystic fibrosis, and sickle cell anemia, and I'm not sure what other ones, but virtually all of their cases that are not those few they do they send to us. So I can assure you there's no way they've done 3,000 single-gene cases of PGD. Not even close.

Q. How about 1300 cases of PGD?

A. We need to define the difference in order for the numbers to be accurate. In order for me to answer the question I need to know what we're talking about. If we're talking about embryo testing of a sample, whatever the sample is, for a gene defect, as opposed to chromosome numbers. If you lump the two together, the numbers are huge. Because this technology of FISH was widely used by many groups, including Cornell for a while. If you talk about single-gene testing, like for cystic fibrosis, I don't know how many they've done, but not anywheres near 1300,

I'm sure.
Q. No, cystic fibrosis they've only indicated they've done 70.
A. Okay.
Q. But are they still sending single-cell analysis to you?
A. Um-hum (affirmatively).
Q. And this has been continuing all during that period of time?
A. Yes. In fact, last week or the week before we received a sample from them.
Q. Okay. Do you interact with Dr. Xu at Cornell in connection with the referrals?
A. No.
Q. Who do you interact with there?
A. I don't, but the team interacts with a woman -- whose name I'm blanking out. But there's a woman there who does it all, who actually, I think, runs the lab, I think. I'm not sure. But we interact with the nurses, and with the embryologists, because we're the laboratory in which they are interacting with if they're sending the sample out.
Q. And do you interact with the doctor or physician who's involved with the IVF there?
A. Almost never. Unless they call because they have a question.

Q. And when they call --
A. Are you talking about Cornell, or NYU now?
Q. I'm talking about Cornell.
A. It's the same for both. I just want to make sure we're on the right institution.
Q. Okay. Now, you also indicate in that letter that the technology can fail. Can you tell me in what manner the technology can fail?
A. Oh, many ways. So the cell that is biopsied may not represent the rest of the embryo. The cell that's biopsied may not have a nucleus. The cell that's biopsied may not be properly transferred to the tube to be sent, it gets stuck on the wall or some other place. The amplification technique that is used to make multiple copies of that DNA can fail, or partially fail, or fail because one or other of the chromosomes aren't there, or there's too many. You can have failures because of DNA contamination. You can have failures because of allele dropout.
Q. And these various ways in which --
A. And more. There's more, but --
Q. Okay. Is there an explanation as to why a laboratory like the one at Cornell would have -- and, by the way, failures can be found before the report is issued, it could be an in-house identification of the failure, is

between three and five percent, is that correct?
A. That's the risk that's quoted around the world in other PGD programs, and in general the genetic counselors quote that number. In our group it isn't that high, but that's the number that's been sort of announced by --
Q. Okay. Can you tell me, when you say that's announced by other groups and around the world, where are these announcements made? What specifically are you referring to?
A. So at scientific meetings people stand up and talk about the error rates that they see.
Q. And you have a specific recollection of people standing -- of particular people standing up?
A. Sure.
Q. Okay. What group or what person in these meetings do you recall standing up and they have an error rate of three to five percent?
A. They don't necessarily say that they have an error rate. They quote that as the rate in the field.
Q. Okay.
A. And I've always thought that was high.
Q. Okay. In other words, individuals have stated at meetings, who are attending the meetings and are working in the field, that the error rate in the field in general is three to five percent, is that correct?

A. I've heard that many times.
Q. Okay. And has that error rate changed over time?
A. Actually the quoted numbers from just last week at the international meetings were still three to five percent.
Q. Okay. So someone got up and quoted three to five percent at the meeting last week?
A. I heard it discussed, yes.
Q. Okay. And who did you hear it discussed from? Who said it?
A. I'd have to go look.
Q. And where would you look?
A. I'd look at the minutes of the meeting that we just had.
Q. And those minutes are circulated?
A. No. They're notes that I would have taken. Or they might be in the abstract. We can look.
Q. And is the abstract circulated for everybody who's in attendance at the meeting?
A. Yes.
Q. And what was the nature of the meeting, what was the group that met?
A. The PGD International Society.
Q. And where was the meeting?
A. France.
Q. And was Dr. Xu there?
A. No.

Q. And your rate is less than one-half of one percent, is it not?
A. No. Our rate runs between one and two, depending on the year.
Q. So each year you have one to two percent misdiagnosis?
A. 1.2, 1.3, 1.4, 1.5.
Q. Now, is that specifically with respect to cystic fibrosis, or is that with respect to all --
A. No. That's all diseases.
Q. And how many do you do a year?
A. I can tell you what we did in 2004.
Q. How many did you do in 2004?
A. I wrote the numbers down. We did 582 cycles.
Q. And you have that specifically available to you, you wrote it down?
A. I wrote it down before I came over here. Because I figured you'd ask.
Q. Okay. And what did you write it down on?
A. (No response).
Q. What did you write it down on?
A. I just wrote it in the corner here on this piece of paper.
Q. Before you came over here?
A. No. I had it in my mind. But I knew the question was coming, so I scribbled it over here so I wouldn't forget

the numbers.
Q. And do you know how many you did in 2009, last year?
A. No. But almost twice that.
Q. And how many failures did you have in 2004?
A. Three.
Q. The Grossbaums was one of them?
A. Yes.
Q. And what was the analysis done on the other two that had failed?
A. One of them was a healthy child that we predicted was a carrier, and one of them was an affected that was picked up on amniocentesis or CVS.
Q. And was it picked up?
A. Yeah.
Q. And did the parents abort in that case?
A. I don't remember. There's no link between those. An amniocentesis is not a search and destroy mission.
Q. I think we explored that at the last deposition, didn't we?
A. I don't remember.
Q. You haven't read your deposition --
A. Months ago.
Q. -- prior to coming here today?
A. No.
Q. The 582 cycles that you described, were they for all

forms of genetic disorders, or just for cystic fibrosis?

A. No. For all forms.

Q. Now, the Grossbaums were described as having a mutation that was -- can be said to be compound heterozygous, is that right?

A. Yes.

Q. Do you know how many of the cystic fibrosis studies that you did in 2004 were for couples who had compound heterozygous mutations?

A. I don't know those numbers off my head, no.

Q. Do you know how frequently you see compound heterozygous mutations to be analyzed?

A. Fairly frequently. Now.

Q. Now?

A. Um-hum (affirmatively).

Q. How about in 2004?

A. We would see them then, too, but it's gone up substantially, the numbers. Because the ability to find the mutations in these different diseases has gone up, because the technology for looking for the mutations is easier. So just a few years ago there weren't very many places that would -- well, cystic fibrosis is different -- but for many of these disorders there wasn't anyone who was willing to screen by DNA sequencing the entire gene looking for what the other mutation might be, so PGD

(affirmatively).

Q. And that would be for 2003 and 2002, is that right?

A. That's correct.

Q. And the use of linkage analysis certainly increases the accuracy and reduces the risk of misdiagnosis, isn't that true?

A. Not in 2004. It was just beginning to be proven to be so, and the manuscripts were beginning to come out showing that it worked.

Q. When you say they were beginning to come out, we do agree that Dresen's group in Europe was reporting in 2001 the success rate for using linkage analysis, weren't they?

A. They were taking two cells in order to get those results, so they were biopsying a couple of cells from each embryo. Most of the clinics we work with don't want to do that, including NYU. And the group in Chicago that was doing it was biopsying a polar body, oftentimes a first polar body and a second polar body and a blastomere.

Q. Is that in all compound heterozygous cases?

A. I don't know. But that was their standard that they reported at meetings and in their papers. And they argued at the meetings that this was a better approach. And this was all kind of coming out. But we had a 1.2 percent error rate, which was significantly less than

anybody else was reporting, so -- and we were having difficulties getting multiplex PCR to make that better or look like it make it better. Theoretically we could see where it was quite valuable, but we were not happy with the results, in those early papers we weren't able to reproduce them.

Q. When you say you were not happy with the results, what do you mean by that?

A. Well, in anything in science and medicine, a manuscript comes out, and this doesn't suddenly make it the gold standard of practice. Because if it was a gold standard of practice, that paper wouldn't even be allowed to be published because it isn't new or exciting. So the papers that were coming out in 2001 were theoretical to start with, then they became one or two cases, take a couple of cells, do the analysis and see what the results are.

The RGI group actually were quite leaders in this, and were showing some beautiful data at the time. But others of us were having difficulties duplicating that. We weren't as good as them perhaps, I'm not sure. But we were not comfortable, with our preliminary when we developed the test for a couple, we were not comfortable with the multiplexing of more than two different mutations at the same time. We didn't have the ability,

nor did we think we needed, because we had such a low error rate, that we weren't ready to be offering something that was just being discussed.

Q. Well, if there was a laboratory as close as Chicago, you having good results with linkage analysis, didn't you see it as on obligation of your relationship with the couples such as the Grossbaums who had compound heterozygosity, to afford them the opportunity to go there?

A. That's up to the doctor to decide what laboratory they're going to use, first of all. And secondly, it wasn't hardly proven until the Goossens paper came out that that was actually working clinically.

Q. And when did the Goossens paper come out?

A. Late 2003. I think. I can't remember. I think it was in the fall of 2003.

Now, the --

Q. And by the Goossens paper you're talking about Improving Clinical Preimplantation Genetic Diagnosis for Cystic Fibrosis by Duplex PCR?

A. Yes.

Q. And you were aware of that paper when it came out?

A. I don't remember when I first saw it, but when I did it was a good group that had some clinical successes, and it was beginning to -- the handwriting was beginning to become quite clear that this was the future. Now, we

were already trying to do it, but we do lots of things in the laboratory as we test for several years before we move it to clinical activities.

Q. Now, when you say you were already trying to do it, can you explain what you mean by that?

A. So we would take hundreds of single cells that we would micropick, as though they were a cell from an embryo. Lymphocytes, fibroblasts, amniocytes, in which we knew what the mutations were in those cell lines. We would pick them and study them as though they were a biopsy from an embryo, blinded. And then we would analyze to see if we could reproduce the results better than the error rates that we already had in our program. And what we were finding was that the -- we would pick up some markers that were very nice to have, but we would lose other pieces of data, oftentimes the mutation. And so to get them to all work together just was a problem. We weren't comfortable that the technology was improving anything. So that's what happens over a period of a few years, you try, you analyze, you compare, you check out to see if the other laboratory's work is reproducible. And sometimes it is and sometimes it isn't. And in the field of IVF there's all kinds of these false starts, but you don't know which one's a false start. So you don't just move it to the clinical arena because somebody

publishes a couple of papers, most of them theoretical.

Q. Well, you do agree in the year 2000 Chicago had published its atlas describing the use of linkage analysis, isn't that so?

A. Everybody knew about linkage analysis.

Q. And do you agree that Dresen's paper was in about the year 2000 or 2001, wasn't it? Dresen.

A. I don't recognize that name. I probably was a graduate student or something.

Q. Or am I mispronouncing it? Is it Dresen? It's D R E S E N. That's the Department of Molecular Cell Biology and Genetics at Maastricht University, that would be in the Netherlands, and it was published in 2000.

A. Let's see.

Q. (Indicating).

MR. STEIN: Let the record show I've handed Dr. Hughes a copy of the journal publication that I've just referred to and he's reading it.

THE WITNESS: Yeah. We could test single lymphocytes and fibroblasts like this. This isn't an actual -- there's no pregnancies here, there's no proof that it works in an IVF embryo. Now, later, soon thereafter, there was. But this is studying lymphocytes, and some blastomeres. Let's see here. Blastomeres were obtained from human embryos that were donated in IVF. So

this is all -- this is a nice paper. It was new, exciting, new possibilities for changing the technology. But it was a long way from clinical implementation, certainly in the United States, except at RGI.

Q. Well, Doctor, let's separate that. It would appear from this article in 2000 out of the Netherlands, as well as the RGI publication in its atlas, that the technology was known by 2000 by these various groups as to how to do it, isn't that so?

A. The ability to do multiplex PCR had been around long before that.

Q. All right. So if these groups --

A. And we were doing it.

Q. Well, when you use the term multiplex analysis --

A. It means having a single cell and looking at multiple places in that genome.

Q. Is that the same as linkage analysis, in your terminology?

A. Looking at those multiple places produces the linkage information.

Q. Okay. So then using that technique as a standard use in their laboratory, RGI was doing it, they had the technology, didn't they?

A. We had the -- lots of people have the technology. The question was, was it ready to be added and was it proved

to be useful and was it better.

Q. Well, if it reduced the --

A. Let me give you an example. The same group who I think are outstanding in Chicago, Svetlana Rechitsky and Buck Strom, they were great scientists, they were working on a technology called FISH. And when you quote these numbers from Cornell with thousands of cycles, those were done with FISH. In fact, the world jumped on the ability to count chromosomes using FISH technology. And now, all of the medical societies that oversee this have said that there's no scientific evidence that this works. There's no scientific evidence that a patient should have FISH testing. And it's written in the practice guidelines of the field by the authorities who you would recognize that direct the way something is performed in medicine. In the society's guidelines of practice it says that there's no scientific evidence that FISH works. Now, it's controversial. We never believed in that technology either, and never performed it. Why? Because we couldn't get it to work with the kinds of reliability we wanted. In the same way in IVF, there's all sorts of steps that are taken to try to improve the technology an get people pregnant with healthy babies. It's done all the time. Many of those fall by the way side as being not helpful, can't be reproduced. So in the first few

years of the year 2000 people started talking about doing this in PGD, and everybody, I would hope, was trying to get this to work because of the theoretical idea that it was going to help and avoid one of the problems with PGD, which is allele drop out. But you have to have a technique that improved it significantly more than what you already had. No more than Memorial Sloan Kettering invents a new cancer agreement and no other cancer programs in the country use it for some five years or ten years while they're assessing it. It doesn't make it standard, just because you publish a paper, doesn't make it standard of care.

Q. Well, when you publish it in an atlas on how to do it, would you say that then it has moved from theoretical to clinical practice?

A. No.

MR. LEUCHTMAN: Object to the form of the question.

THE WITNESS: The atlas is written by the people who are promoting their own science.

BY MR. STEIN:

Q. All right. Now, in fact, had you been provided with blood samples from family members of the Grossbaums, you would have done linkage analysis, wouldn't you?

A. We would have tried.

EXHIBIT 3

IN THE UNITED STATES DISRICT COURT
IN THE DISTRICT OF NEW JERSEY
----------x
CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually and as Guardian ad litem of the infant, ROSIE GROSSBAUM,
Plaintiffs,

-against-

Index No.
07-CV-359

GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK P. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITAL CENTER, both corporations of the State of Ne York, ABC CORPORATIONS 1-10 and John Doe DOE,
Defendants.
----------x

DEPOSITION OF CHARLES STROM
New York, New York
June 24, 2010

Reported by:
Judith A. Frost
Job No. NJ263710

Condensed

Page 164

Genesis Genetics in this case, and Dr. Mark Hughes.

MR. HAMAD: Jay Hamad from the office of Marshall Dennehey on behalf of the defendants.

MR. STEIN: Lewis Stein from Nusbaum Stein Goldstein Bronstein & Kron on behalf of the plaintiffs.

EXAMINATION BY
MR. LEUCHTMAN:

Q Mr. Strom, we met on May 4 when I questioned you at some length about this case. You have in front of you a file, and I believe we inventoried it during the first session of your deposition.

Have you added anything to that file?

A No.

Q Since we last convened, let me ask you this. Is there any correspondence to or from Mr. Stein that you did not bring with you?

A Just about this particular arrangement. The logistics.

Q Nothing substantive about the case?

A No.

Q Have you reviewed the transcript of

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your May 4, 2010 deposition?

A No.

Q I want to point out one thing, and I think the court reporter sort of outdid herself, I could find only one typo, but I want to give us all the opportunity to straighten that out.

It's page 102 where you were asked, I was asking you your opinions on whether you believed that Dr. Hughes and/or his lab were coersive and abusive in trying to coerse the Grossbaums in having amniocentesis and your answer, it says here "and effective child"?

A That was meant to be affected.

Q I suspected that's what you meant, and it is probably what you said.

A Right.

Q You have also not read the transcript of the deposition of Dr. Kangpu Xu, correct?

A No, have not.

Q Have you ever been informed about the contents of that deposition?

A No.

Q Have you read the second deposition of Dr. Mark Hughes when he was deposed as an expert?

A Yes. Wait a second. Is Kangpu Xu the

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one you sent me? I must correct myself. Yes, I did read the second deposition. I didn't know how the last name was pronounced, I'm sorry.

Q You read also the second deposition of Dr. Hughes?

A Yes, those two I would say.

Q Since that time have you read any other depositions such as, and we kind of or I kind of belabored this is in your last deposition, of either of the plaintiffs or any of the NYU people?

A No.

Q Or any synopsis of those depositions?

A No.

Q Since we last convened have you reviewed or read a synopsis of the NYU records?

A No.

Q Did you ask for any of these materials and not receive them?

A No.

Q Now, let me ask you if you can remember in Dr. Kangpu's deposition transcript, there must have been areas where you disagreed with him.

Can you tell me as we sit here right now what those area were?

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MR. STEIN: Let me put my objection on the record. Going from memory into the contents of the deposition of many pages to me is an unfair question.

MR. LEUCHTMAN: He said he can't remember.

A I said I can't remember either way.

Q I'll be more specific then.

There were a handful of things in Dr. Kangpu's deposition that I want to ask you about.

He said that polar body biopsies are not commonly done in the United States and they are not a mainstream approach.

Do you agree or disagree with that?

MR. STEIN: I object to the form of mainstream, but if the doctor understands what you mean.

A Polar body biopsies are commonly done, but only done in one center in the United States.

Q Is that R.G.I.?

A Right.

Q Would you agree with Dr. Kangpu that polar body biopsies are not standard of care in this country?

A I would agree.

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually, and as Guardians ad litem of the Infant, ROSIE GROSSBAUM

Plaintiffs

vs.

GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, Both Corporations of the State of New York, ABC CORPORATIONS: 1-10 and John Doe

Defendants

_____/

Certified Transcript

Docket No. 07-CV-359

GARRY CUTTING, M.D.

April 24, 2010

(TITLE PAGE Continued on the Next Page)

Reported by: Linda Lindsey, CSR

The deposition of GARRY CUTTING, M.D. was held on Saturday, April 24, 2010, commencing at 1:12 p.m., at the Tremont Plaza Hotel, 222 Saint Paul Place, Suite 506, Baltimore, Maryland 21202, before Linda Lindsey, CSR, Notary Public.

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(APPEARANCES CONTINUED on the Next Page)

APPEARANCES CONTINUED:

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ALSO PRESENT: Stanley Dickson, Genesis Genetics
Lynn Harrison, Paralegal

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A. Training to take care of patients, particularly pediatric patients with a variety of different conditions.
Q. Can you define pediatrics for me?
A. Pediatrics is children from neonatal to 18 years of age.
Q. Okay.
A. Sometimes a little longer, in the twenties, depending on exactly the case and condition.
Q. Okay. Um, now is it fair to say your CV, and -- which I have a copy of here and I believe is to the tune of 31 pages?
A. Yes.
Q. Which you produced to -- to -- to counsel?
A. It's the one I sent to Mr. Lewis.
Q. Is that an accurate -- is that -- let's strike that.
Is your CV an accurate -- an accurate description of your medical experience?
A. Yes.
Q. So if there is anything worthwhile in that you did in the medical -- in the medical field it's in here?
A. Sure.
Q. Okay. Now, after your -- your residency in

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pediatrics you completed a fellowship, correct?
A. Correct.
Q. Okay. We'll -- what did that -- strike that.
What was the concentration of that fellowship?
A. Genetics, medical genetics.
Q. Okay. What does that mean, medical genetics.
A. It's training in the care, diagnosis -- let's start, care and treatments of patients with a variety of genetic disorders.
Q. Can you be -- be more specific? Tell me exactly sort of what that entails?
A. Well, patients whose disease is primarily caused by abnormalities in specific genes.
Q. Okay. Yeah, I'm just trying to get an idea sort of what kind of things did you do? I mean, did you --
A. I would be consulted on patients who were, where the physicians felt that there would be a genetic case because a familial recurrence of children of the same family. So, like CF, two children same family have the disease, so we get consulted for that. We get Sickle Cell Disease. We get consulted for skeletal abnormalities --
Q. Fine.
A. -- a whole variety conditions. And they

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included both children and adults.
Q. I see. So it's -- it was people already born, obviously, that's what I was trying to focus to. People who are already born --
A. Oh, no, not just that.
Q. Okay.
A. No, we also did consult on prenatal cases as well.
Q. Okay.
A. So we included prenatal counseling. The -- the discussion of things such as teratogens that may affect a pregnancy, genetic conditions that may affect a pregnancy.
In addition to my training, I also trained in clinical laboratory genetics, as well as this is called molecular genetics, which I'm board certified in, and as in biochemical genetics. So that was undertaken during the time that I was training in medical genetics.
Q. So biochemical genetics and clinical genetics?
A. And, well, clinical genetics, biochemical genetics and molecular genetics. The molecular is in the diagnosis of disorders by examination of DNA directly.
Q. Okay. Now -- okay. So, what specific

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function did you do during your fellowship as it pertains to, um, prenatal involvement with patients?
A. So we would counsel patients who had prenatal conditions. We would see patients who had undiagnosed prenatal conditions where there was concern. We would see women who had advance maternal age, which I'm sorry to say, is beyond 35 years of age who have were at higher risk for children with abnormalities, such as Down Syndrome.
If I'm going too fast, please tell me to slow down.
It would be working with families to tell them about the results of test, such as sider genetics tests or -- or DNA based tests and the results and counseling them on those results. With working with them to make decisions about whether to continue the pregnancy or not to continue the pregnancy, particularly if the pregnancy was affected.
Q. And that was during your fellowship?
A. That was during my fellowship and I continue to do that. That's why I'm carrying the beeper today, if this condition came up today at Johns Hopkins, I would be called for it and I would go in and talk to them.
Q. Okay. Now, as part of your fellowship --

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need to.
Q. As soon as you objected I said I will rephrase it.
Now, doctor, please -- right now I'm going to -- I'm looking at this first paragraph here and it says, I have reviewed the records that were provided by Genesis Genetics, the New York University School of Medicine, as well as depositions of Mark Hughes, Dr. Licciardi, and Alexis Adler, and publications involving multiplex marker analysis provided by Dr. Rechitsky, fair?
A. Yes.
Q. Okay. Is that a listing of things you reviewed before authoring this report?
A. I believe it is complete, but I would say that is an estimate, I can't -- I can't --
Q. Well, can you think of anything that you reviewed before authoring the report --
A. Oh, other than --
Q. -- that --
A. -- other than the literature, I don't cite specifically here.
Q. Okay.
A. And the information is available in textbooks and so forth.

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Q. Okay. All I'm -- by --
A. It's just not citing -- that's, if I can digress, as a scientist, I have to say that we try as best as we can, obviously, to disclose what sources we've had. So, if you asking me in that context, I'm trying to be as complete as I can, so, yes there was other literature and so forth. But as far as legal documents, I believe that that's a complete list.
Q. Okay. I'll actually be more specific. As far as documents that were generated, medical records, deposition testimony, um, anything else that was provided to you by Mr. Stein that is not medical literature medical, medical resource is this all that you reviewed before authoring your report?
A. Yes.
Q. Okay. And then after that sentence you spend, you, I think indicate, you write, "as I understand" and then you complete the paragraph with couple of more lines, fair?
A. Yes.
Q. Okay. And in those few lines you give the history, um, of the presentation of the patients and the, um, the, um, outcome with -- of a child -- of a child with -- that's affected with cystic fibrosis fair?

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A. Yes.
Q. Is it fair to say, beginning with, as I understand and con -- and -- and concluding with was found to be affected with cystic fibrosis that that portion of the first paragraph of your report contains the history that you felt was relevant to analyzing this case?
A. Yes.
Q. Okay. There was something else that is important fundamentally important to this case, to your analysis you would have put it in that -- in those -- in that paragraph, fair?
MR. STEIN: I object to the form of the question. Go ahead.
Q. I think the -- would you like me to rephrase it? Or do you understand what I'm saying?
A. (Holding hands up.)
Q. Okay.
A. My answer is that this is a distillation of my understanding of the case. It may not contain all elements that are essential to understanding and appreciation of the issues, but it is an attempt on my part to be as brief and to the point as possible.
Q. All right. Now, just so I can limit my time with you, Doctor, is it fair to say that all the

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criticisms you have of NYU are contained in -- strike that.
All the opinions you have regarding NYU's performance in this case are contained in the second paragraph of the first page of your report?
A. This is a distillation of my opinion of the case. It may not contain all my criticisms.
Q. Doctor, you've authored eight reports before, correct?
A. Correct.
Q. Did you understand -- did you understand that when you wrote this report, Doctor, that you're -- you -- you were putting on notice --
A. Um-hum.
Q. -- the defendants in this case as to what your opinions regarding their performance are?
A. Yes.
Q. Okay. Do you -- do you understand that you're bound by the four corners of this report --
MR. STEIN: I object, that's a legal --
MR. HAMAD: -- and that's --
MR. STEIN: -- conclusion that has much definition and complicated definition for you to ask the doctor a legal question.
MR. HAMAD: Um --

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A. We -- we attempt to work always through the physician because the physician and/or genetic counselor are the one who contacts us.
Q. Yeah?
A. No, I'm done.
Q. How is PGD different from what you routinely do in your lab?
A. If we're talking about blastomere biopsy which the removal of one cell or two, depending on which lab you do and how you do it, it involves a much smaller amount of DNA and it requires exquisite levels of, um, testing ahead of time to assure that you get an accurate diagnosis, because unlike in the case, as you have been indicating, that when you get a large amount of DNA from a CVS sample or from a blood sample of a patient we're getting six picograms of DNA on average from one cell.
Q. This is in PGD?
A. PGD, sorry.
Q. All right.
A. So the test and the importance of being accurate and having plenty of additional assays there to be sure you achieve accuracy is absolutely paramount in PGD because it is the more challenging area of genetic diagnosis currently available.

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Q. PGD is?
A. Yes, by fair.
Q. Now, is the sample use in PGD, if you know, different from the samples you use in your lab?
A. Yes, because they're based on blastomere, which is single cell from an embryo. CVS is actually a sample of the fetal portion of the placenta. Amniocentesis is actually cells shed by the embryo that is present in the amnionic fluid that is drawn when a needle is placed into the --
Q. Now, if a cultured sample from a cytogenics lab or other patient tissue samples has one or two milligrams in it, and the PGD sample has two picograms, then would you agree that there's one billion times less DNA in the PGD sample?
A. Has six picograms but, yes, it has quite a bit less.
Q. On the order of of a billion times less in PGD?
A. Well, what's important is the genome equivalence not the amount of DNA.
Q. But I'm -- I'm just asking you as to DNA?
A. Okay. Fine.
Q. Are we agreed?
A. We're agreed.

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Q. Okay. Would it be correct to say that PGD pushes molecular DNA testing to the limit because it tests, first of all, one cell, which is the smallest unit of life?
A. Yes.
Q. And for one gene which is smallest unit of inheritance?
A. That's not correct, but anyway, yes, we'll say --
Q. For one gene?
A. We'll stick with it.
Q. All right.
A. I'm being a scientist type, let me shut up, yes.
Q. And more often times a change on one A or T or G or C, character in 3.3 billion DNA letters of the human genome?
A. Yes.
Q. Is there any lab testing you're aware of that's anymore complicated than PGD?
A. Yes.
Q. And what would that be?
A. There's lots assays that involve protein biology which involve use of antibodies which have actually quite tricky characteristics in order to

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properly identify the proteins, and these proteins can actually predict whether you're going to get cancer, you're going to get -- you're actually have metastasis of cancer.
In fact, there's a whole range of these assays available, and they're quite complex to carry out and do, and they acquire exquisite levels of controls and inter assay controls and so forth. So, yes, there are more complicated ones than this.
DNA is a very simple thing to work with, the simplest chemical we probably work with.
Q. Now, your laboratory does not at present do PGD?
MR. STEIN: He said that.
MR. LEUCHTMAN: Yes, I know, it's foundational.
A. Yeah, at present.
Q. Was there a time when you did that?
A. Yes, yes.
Q. When?
A. Over the past couple of years we've done two cases for CF.
Q. Other than that have you ever been involved in PGD?
A. No.

Q. Specifically, you're not involved in PGD directly in the year 2004?
A. 2004, no, I don't think we -- no, no.
Q. Okay. Well, then let's clarify when you say you have done two --
A. Two cases were done after 2004 and before today.
Q. All right. Well, you said the last couple of years?
A. No, no, you're right. You're absolutely right.
Q. Okay.
A. I don't mean --
Q. Well, let's narrow that down because it's important, I think, in this case.
A. Yes.
Q. When were these two cases --
A. I would say --
Q. -- PGD cases for CF in the past couple of years?
A. -- in the past probably couple of years, I'm doing it again, sorry. Probably more than 12 months ago, but not more than three years ago.
Q. Okay.
A. Is about when I recall them. They were about

one and a half to two years apart, if I recall correctly.
Q. So, as -- as best you can recall as we sit here today, the first one you did was in perhaps 2007?
A. Yes. Something like that.
Q. And no earlier than that?
A. Yes, about that.
Q. All right. And you were not involved in any form or fashion directly in PGD in 2004?
A. In delivering the test. We certainly were spending time doing assays to develop the tests, yes.
Q. But you weren't doing PGD testing?
A. No.
Q. No, you were not?
A. No, you're correct.
Q. The two -- the two PGD cases you've done in last three year were for cystic fibrosis?
A. Correct.
Q. And what means did you do to do those tests?
A. A single cell from a cleavage embryo, so it was eight cells, we took out one cell, in the same way this method was done and did a diagnostic to see it.
Q. When you say the same way this method was done --
A. Okay.

Q. -- the same thing that Hughes did in this case?
A. Yes, well, as was done by both NYU and Hughes.
Q. Okay.
MR. HAMAD: I'm sorry. I may have missed something. The last couple of years? What -- when was the timing of these tests?
MR. STEIN: Between 12 months and three, he said. Twelve months and years?
THE WITNESS: Yeah.
MR. LEUCHTMAN: Yeah.
MR. HAMAD: Go ahead. I'm sorry.
MR. LEUCHTMAN: And no earlier than 2007.
THE WITNESS: Yeah.
Q. Well, did -- did the two tests that you did three years or less ago involve genomic markers?
A. Yes.
Q. Did they involve polar body biopsy?
A. No.
Q. Do you agree there are many safeguards that need to be put into place in PGD testing over and above, for labs that do not do it?
MR. STEIN: Over and above what?
MR. LEUCHTMAN: Well, for labs that do testing, such as -- as Dr. Cutting does. There are

safeguards that exist for PGD that do not exist in -- in the diagnostic labs -- in diagnostic labs such as the one that Dr. Cutting operates.
MR. STEIN: I object to form of the question, but he can answer it.
A. Um, we did offer PGD within our lab using the same safeguards that we use for the other tests. It's just as important to develop the right assays for a CVS test to make sure it's not contaminated with maternal cells, which is a maternal cell test we do using linked marker, and we've being doing for a decade to be sure that we don't have contamination that leads to a misdiagnosis. So we take the same level of care with every test we do.
There are different technical challenges in executing the test which require additional or other approaches and so forth, PGD is one that requires some additional tests, and there are other ones that we do in our labs that do require, also, additional marker tests, but I give you the example, we've been using linked markers, genomic markers for over ten years for maternal contamination CVS. To prevent --
Q. For maternal contamination?
A. Yes. That's finding mother's cells in with the baby's cells when you do the sampling of the

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placenta. And that was found, actually, some ten, 15 years ago to be a major cause of misdiagnosis, and the entire field then realized that in fact the way to do this was to do a maternal test, a contamination test using these markers, these genome markers that you mentioned.

So now laboratories do this standardly. And this was adopted quite rapidly when it was discovered this is an error that could cause a misdiagnosis in prenatal testing.

Q. And this was when?

A. Oh, this would have been back ten, 15 years ago.

Q. Now, are you using gene chips SNPs or microbead's or did you use it in two PGD tests that you did?

A. No. No.

Q. All right. And why not?

A. Not needed.

Q. The PGD that you did for cystic fibrosis was it for a variety of mutations or just for DeltaF508?

A. Just for DeltaF508.

Q. And was there a pregnancy in each of those?

A. Yes.

Q. How many clinics do you receive PGD biopsy

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samples from?

A. Zero. Well, the only cases, those two cases were from Hopkins. We don't do any cases.

Q. How many labs in the country do PGD testing?

A. Two or three. As far as I know.

Q. Given PGD is a growth industry -- well, do you believe that it is?

A. No.

Q. And why not?

A. It doesn't look like it is. It is in Europe it appears to be a more, but I'm not sure in the United States whether it's a growth industry.

Q. Well, do you have, um, a reason or do you have an idea why the number of labs doing PGD has not expanded from the two or three that you say exist at the present time?

A. Um, I think there's been some concern about the number of misdiagnosis that have been -- occurred in these cases lead IVF physicians to be a little concerned about doing this testing and expand it. Certainly major institutions, also, like my own, have been concerned about getting into this business unless we can provide high accuracy testing.

Q. You're saying --

A. I apologize, if you don't mind --

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Q. No, I didn't mean to interrupt you?

A. -- if I continue.

So, it's probably a multiple of things. It's like doing very risky surgery for example. How many people are going to take on risky surgery, particularly when they, major centers here there's been issues or problems, even though, at the same time we've witnessed that Europeans have actually done an outstanding job of making this a high quality offering, an option for couples who are at risk for single gene disorders.

And it's -- it's a dichotomy that we can't -- I would have to say that there are several reasons. The adoption of the technology, although the technology is challenging and yet the Europeans have gone ahead and actually fully implemented tests using as we were talking before, SNPs, and chips and everything else. We in the United States have not progressed in doing this case.

Q. Is -- is the view in the United States there is a high level of inherent risk within this country in CVS or PGD? And that that prevents --

A. I can't --

Q. -- it from being more widespread?

A. You're asking me do I know what the word on the street is. Sorry, I don't know what the word on

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street is. All I can say is that when I go to a few of the meetings where I interact with some colleagues, for for example with their own IVF unit, who have interact with others, um, the concern is they understand that it's tricky, it's a difficult test to -- to do because it's on the basis of one cell.

They are somewhat frustrated that Europeans seemed to have sold, not just Europeans but people in the Middle East and other places, that have sold these things. There's a question as to why not we've not brought them into more full play in United States.

Q. Which Europeans do you have in mind when are addressing?

A. Well, Peter Braude and his group in the UK, there's Alan Handyside, is another group, Dagon Wells is in Europe -- there -- he's also in England, he's Oxford, so that's a British group. There are groups in France, Germany, no not Germany. Germany is one place because of their own guidelines regarding diagnostics and prenatal that does not allow it. Netherlands, so forth.

In fact, there's this organization called ESHRE, that's this European Society for Human Reproduction Endocrinology, that's actually been in a leadership position, putting all of the cases together,

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Q. So it's a mixture it isn't just PGD?
A. Yes. Yes, it's IVF. PGD is part of it.
Q. Have you ever presented a paper on preimplantation genetics?
A. A -- a.
Q. Yeah.
A. Have I presented on it, yes.
Q. Okay. Where and when?
A. At the meetings last week. I was invited to present on it.
Q. And what did you present?
A. I presented on the issues surrounding the development of PGD tests in the clinical environment.
Q. And is that presentation reduced to writing anywhere?
A. There should be a -- not reduced to writing, no, just slides.
Q. Have you ever been a member of the PGD International Society or PGD group of scientists in United States or Canada?
A. No.
Q. Or anywhere in the world?
A. No.
Q. Is it fair to say that while you're an expert in cystic fibrosis that you are not an expert in PGD?

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A. I'm expert in genetic diagnostics, and this is a genetic diagnostic test.
Q. So, you're an expert in the G D but not the P?
A. Yes. Thank you.
(Laughing.)_
Q. All right.
A. I agree with you.
Q. And therefore are --
A. He's displaying a sense of humor which I like retained.
Q. -- not an expert preimplantation genetic diagnosis?
A. I have spent seven years developing tests in our laboratory along with the IVF unit at our own hospital evaluating the methods for developing PGD testing. I presented at the COPS meeting and I was invited to present at this PCRS meeting, so somebody must think I know something.
Q. Well, I -- I certainly have been convinced in the last three hours that you know quite a bit, the question is are you an expert in PGD?
A. Am I --
Q. You know some of the issues bearing on PGD?
A. Yes, I know the issues on -- when you say an expert, what -- what -- I'm an expert in the -- all of

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the concepts underlying what needs to be done for PGD.
MR. STEIN: Okay.
THE WITNESS: I don't know how to say it. I understand the whole thing, that's the best I can say. I understand all the concepts as a genetic diagnostic, running a laboratory 16 years. I understand the concepts of doing single cell analysis, we've done it in our lab, we've done two cases.
So I would say that while -- while -- would you say that if expertise is granted by doing thousands of cases, I haven't done thousands of cases. Do I understand all the complications and other issues related to because we spent an extensive amount of time doing validation and have I kept with the literature and gone to meetings, yes.
Q. Did you ever work with Dr. Strom before?
A. Through collaboration on, I believe accumulating information about the frequency of CF mutations, I believe. Not directly. No, not this collaborators like we work on an assay.
Q. Well, --
A. I believe you'll find in the literature that we might be on the same papers because we both contributed to a knowledge base.
Q. Do you know Dr. Strom personally?

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A. I've met him.
Q. Under what circumstances?
A. Oh, meetings and like American Society of Human Genetics and things like that.
Q. Were you and he ever colleagues?
A. No.
Q. Did you ever work directly with him on a paper?
A. No.
Q. So, some -- some sort of loose amorphus kind of collaboration?
A. Well, there's also people, there's probably other colleagues you know in the field, right? And some you know better than others you work with. So, I have met Dr. Strom, I know who he is. I know we have contributed to group efforts regarding CF.
Q. Have you ever testified on behalf of Dr. Strom or against him?
A. No.
Q. Have you ever been -- have you ever reviewed any cases involving Dr. Strom without testifying?
A. No.
Q. Do you have any connection or have you ever had with Quest Diagnostics?
A. Do I have any connection with Quest

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heterozygous", like this couple here, ADO, I can only read so far upside down, compound heterozygous, I'll leave the autosomal dominant conditions, the consequences of ADO can be catastrophic, as misdiagnosis and subsequent transfer of affected embryos can occur. Indeed ADO is the most likely cause of reported errors in PGD of cystic fibrosis in which affected compound heterozygote embryos were misdiagnosed as carrier embryos because the analysis could only detect one of inherited things. That's pretty explicit, isn't it?

Q. This article by Thornhill and Snow doesn't address --

A. Oh, yes, it does. It addresses the use of multiplex markers in a later portion as demonstrating, reducing the risk of error due to ADO occurring in cases of compound heterozygotes, and it clearly shows that that is a method available. And this is in 2002, two years before this case occurred.

Q. And what -- what publication is that?

A. It's Thornhill and Snow. And it was in a journal in JMD. I don't have the whole thing here, I just have portions of this one. This -- this is pretty classic -- I just brought the.

MR. STEIN: I may have that.

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THE WITNESS: You have the whole thing.

MR. STEIN: Yeah.

THE WITNESS: This is pretty classic summary. A very nice review.

Q. This Verlinsky --

A. Right.

Q. -- article does not address the multiplex, does it?

A. Yes, it does. Fact, simultaneous amplification of the CF DeltaF508 with a linked marker reduced the ADO rate by more than an half, irrespective of the use of conventional or this other fancy PCR they use. With an additional second marker in multiplex PCR, the ADO rate was further reduced by half and was completely absent with the simultaneous amplification of three markers.

This was in atlas of preimplantation genetic diagnosis. Seemed to be a bible the year 2000 by Verlinsky and Kuliev, which many of us starting up a genetic diagnostic for PGD, certainly we read this and we said, well, we've got to use, obviously, linked markers. There's no way you would put it in play this was 2000.

MR. STEIN: Excuse me, do you want, gentleman, want the journal reference for the Thornhill article?

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MR. LEUCHTMAN: Not right now.

MR. STEIN: Okay.

Q. Now do you know for a fact whether reproduct -- as of early to mid-2004 Reproductive Genetic Institute, RGI, was doing multiplex testing for, or genomic marker testing for --

A. It's my understanding they were doing marker testing as well, yes, multiplex testing.

Q. For cystic fibrosis?

A. As of 2004.

Q. Yeah, yeah, in early 2004?

A. At the time this was case of done. At the time this case was done.

Q. How do you know that?

A. It's been indicated on -- by, first of all, indicated that they used this. I heard from Verlinsky at a genetics meeting, oh, it must have been, American Society of Human Genetics 2000, 2001 that he presented that his lab was doing this.

Q. Were they routinely doing it to your knowledge?

A. I assume the way he presented was that they were.

Q. You don't know?

A. I don't know for sure, I can't tell you. But

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they certainly indicated that they were doing the testing. When they presented this data.

Q. Do you know Repro Genetics in New Jersey, Dr. --

A. I don't know.

Q. Do you know whether -- you said you never heard of Genetics and IVF in Virginia?

A. No, not really. No, no, I mean, that's just not one I think about, I think of just Repro and --

Q. So you don't know?

A. No, no.

Q. Or Cornell Medical Center in --

A. I don't know if Wells was doing it, I don't know, I don't.

Q. Do you know how many of these labs besides maybe RGI were using genetics markers at all, let alone in testing for cystic fibrosis?

A. I -- I know it was indicated that it's good to use it for causes. I don't -- I don't know for sure, no, I don't. But I think this is all discoverable. You could certainly ask these laboratories --

Q. And you don't know --

A. It's not worth me guessing. We can find this out definitively. It's straightforward.

Q. Well, I'm asking what you know and I don't

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think you have to guess you know.
A. I don't want to guess. Well, he told me not to guess, I'm telling you I'm guessing, so I don't want to guess anymore.
Q. Well, the questions you're being asked are, do you know such and so --
A. I --
Q. -- and if you don't know you're not guessing you don't know?
A. Yeah, okay. I was under the impression --
Q. Correct?
A. -- other labs beyond of RGI because the presentations given by Dagon Wells and others --
Q. All right.
A. -- they were using markers. I can't say for sure. You said it as a fact, I don't know for a fact.
Q. Okay. But you don't --
A. But it's my impression labs beyond RGI were certainly aware of this information and --
Q. I didn't ask you were they aware, I asked were they doing genetic marker testing?
A. Do I know for sure, yeah. Sorry. I'll say I don't know.
Q. Do you know how many, if any, of the labs use genetic markers for two mutations?

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A. Well, it's the same question, so I don't know.
Q. How much more complicated is it to test for two mutations than one using genetic markers, genomic markers?
A. How much more?
Q. Yes. Is it more complicated?
A. Okay. Let's start there. Yes, it is. How much more --
Q. How much more?
A. -- you're hitting two targets, you're asking for two targets to be assayed instead of one.
Q. So is it twice as complicated or somewhat?
A. Not really because it's not a doubling of the effect, you're still doing only one PCR method in which now you put in two set of primers.
So, in fact, yes, it's more complicated but it is something that, um, can be built into the test. It is more complicated, yes, because you're trying to hit two targets. Is it you actually do a whole new assay or some other thing, no.
Q. All right. Now, this question I'm going to ask now is not whether you think they should have done or -- or whether they knew about it or anything of that nature, I want you to listen to the question literally and answer it.

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A. Sure.
Q. Do you know whether in early to mid-2004, the average PGD provider with reasonable skill and care in the United States used genetic marker testing for cystic fibrosis in individuals undergoing PGD?
MR. STEIN: I object to form of the question because you -- because haven't defined average. You talk -- only know that there's three people doing it, what's the average.
MR. LEUCHTMAN: Well, I'm taking from the jury instruction.
MR. STEIN: Well --
THE WITNESS: But --
MR. STEIN: Just take it from the facts.
THE WITNESS: And I don't --
MR. LEUCHTMAN: Now that you've coached the answer we'll --
THE WITNESS: Well, he hasn't said anything. What do you mean by average? Was it reasonable to expect?
Q. I didn't ask you that.
A. Okay.
Q. Let me read the question again it's important question in this case.
MR. STEIN: You say it's an important question

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in case.
Q. In my opinion it's an important question?
A. I grant you, I understand. You feel it's an important question.
Q. I did write it here and I will show it --
A. I want to give you --
Q. -- of you want.
A. Yes. And I -- I want to give you, yes, the best answer.
Q. Do you know whether in the early to mid -- in early to mid-2004, the average PGD provider with reasonable skill and care was using genetic markers for testing for cystic fibrosis in individuals undergoing preimplantation genetic diagnosis?
A. The average --
Q. And that's in the United States?
A. So, if it were two out four, I think probably, yeah, two out of four would do it. Because I'm under the impressio Repro was doing it. I'm under the impression one of the other labs was doing it because their presentation I recall seeing. I know RGI was doing it and I believe, at least, one other lab. So that's an average of two out of four, so that's average, yeah.
Q. Do you know whether?

A. Do I absolutely know? No. You asked my impression.
Q. So you don't know what they were doing but you -- you sort of think that maybe --
A. Well, you're asking me something from seven years ago, do I remember exactly all the labs that were doing it, when I was at the different meetings, when -- this presented considerably at the American Society of Human Genetics, I do remember and the American College of Human Genetics.
Several labs were presenting they were doing this, certainly Verlinsky's group was, and so were others.
Do I remember all those? I don't. Was my strong medical impression or impression that there more than one lab doing it and that -- this was because of these publications becoming a reasonable thing to do in all of these cases, particularly the compounds heterozygous, I would say yes. So, that's my impression, best I can recollect seven years ago in 2004.
Q. Is it necessary to get DNA from family members other than -- than the involved couple in order to do testing with genetic markers?
A. Yes.

Q. Are -- do you have any criticism of Dr. Hughes, or Genetic relating -- Genesis Genetics relating to any communications with the Grossbaums other than what you've already talked about?
A. You mean with -- with this communication here?
Q. Beyond the two that you testified to. You said he should have talked to them about allele dropout?
A. Yes.
Q. And he should have --
A. Informed that -- that his lab did not do the multiplex test where other labs did, at least one other lab we know was offering it. Um, and was there any, I'm sorry, I apologize, I'm getting a bit fuzzy.
Q. Do you have any criticism of any communication with the Grossbaums by Dr. Hughes or Genesis Genetics other than what we've just talked about?
A. Give me one second to think about that answer, please.
Q. Sure.
A. I think I would have to say no.
Q. Do you have an opinion as to whether the -- there should have been any direct communication between Mark Hughes or anybody else at Genesis Genetics and the Grossbaums after their conversation that's memorialized

in this PGD Informed Consent Phone Review, on March 25?
In other words, should he have talked to them about anything, if they didn't call him after March 25, 2004?
A. Did he have a duty to call them --
Q. Well, in essence?
A. -- contact them, to follow them up? Yes.
Q. Well, not to follow them up after she got pregnant?
A. Okay. Pregnant --
Q. Okay. Before the implantation?
A. Um, it's -- I know we all want to get out of here, give me a second to think about this one. Did he have a duty to follow them further?
Q. That's not what I asked.
A. Okay. That's why I'm restating it.
Q. All right.
A. Because maybe I misunderstood --
Q. Should he have spoken with the Grossbaums between --
A. You say should he this is so ambiguous.
Q. All right. All right.
A. Should he have spoken --
Q. And you're --
A. I'm not trying to -- I'm just not sure what

you're asking.
Q. All right. Let me rephrase it then.
A. Yeah, please.
Q. In your opinion did Dr. Hughes or anyone else at Genesis Genetics have duty to speak to the Grossbaums about anything between the discussion Mark Hughes had with them on March 25, 2004 and the date of the implantation, which I believe to be July 17th or 19th?
A. To speak directly to the Grossbaums?
Q. Yes.
A. No.
Q. All right. And what is the basis of your saying no to that question?
A. Well, I would have hoped that all the information that should have been communicated as far as the risk and everything else would have been done in phone interview.
Q. Do you agree that the IVF physician or physicians are and should be the primary contact with the couple in an IVF situation, even if it involves PGD?
A. Yes.
Q. And do you agree that the typical PGD provider, once he returns or once he reports on the

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present time, you and your lab?
A. FSH testing for PGD, no.
Q. No. Well, you're not doing PGD?
A. Right.
Q. You didn't -- did you use FSH testing when you did the --
A. No.
Q. -- two cases in the --
A. No.
Q. -- last three years? Why not?
A. It's not necessary for single gene testing.
Q. Would -- would you have described FSH testing as standard of care at one time when it was generally popular and used in the PGD community?
A. I'm -- I'm really not an expert on the FSH testing side of PGD. I'm on discussing the single gene diagnosis side of PGD.
Q. Do you know whether in early to mid-2004 the average PGD provider with reasonable skill and care would have used FSH testing for cystic fibrosis in undergoing preimplantation genetic diagnosis?
A. FSH testing can't make a diagnosis of CF, unless there's a deletion known and the deletions is also within the reason, and even that would be tricky.
So this is -- FSH is a different assay. So

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look at chromosome compliment, are all the chromosomes there, and are they missing and so forth, that's what the FSH test does.
Is it -- is it a Down Syndrome case, for example, where there's three copies of chromosome 21. Because the FSH, which is a little probe, can light up each chromosome 21. And if you see three signals you know there's three 21s.
So, you say, okay, embryo has three copies of chromosome 21, that is going to lead to Down Syndrome. That's how FSH testing is done.
That condition is different than this type which is one nucleotide -- I'm sorry if this is redundant.
Q. Well, do you know whether or not there was a time when the PGD community by and large, with the exception of Mark Hughes and perhaps others, were doing FSH testing in an attempt to do preimplantation genetic diagnosis?
A. Of CF? No, you never use FSH for CF.
Q. Nobody ever did?
A. For CF, for cystic fibrosis?
Q. Yes.
A. For this condition? I don't know of any case.
Q. It doesn't work?

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A. It's a different technology, yeah. Does that make sense?
Q. Yes. What are polar body biopsies?
A. That is the removal the polar bodies which are generated during the development of the -- of the egg.
Q. All right. And generally speaking polar body biopsy is done because certain hospitals in certain countries don't allow invasive testing on embryos themselves?
A. That is an alternative. Yes.
Q. Okay. And it's an alternative mainly in situations where going into the embryo is verboten by either early legal authority or --
A. Well, that's one reason to do it, yes.
Q. All right. Is it standard of care to do polar body biopsies?
A. Are we going to get in standard of care discussions again, and my knowledge of whatever everyone does and does -- polar biopsy, from what I understand is a technically challenging assay to do.
It has been mastered by a subset of the PGD labs. RGI has -- has championed it and Uri Verlinsky championed, and demonstrated, had some very, in certain circumstances, some very good uses.
And certainly as you point in Europe where one

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is not able to manipulate an embryo after -- so post-fertilization that is used. So that's my understanding of it. We've never used it and I do not know more than that. I can't give you any more expertise.
Q. Can you tell me whether or not as of 2004 polar -- polar body biopsies were routinely done in the United States?
A. Well, certainly RGI was offering it. RGI, the lab in Chicago was offering it. I don't know about the other ones.
Q. Are they being used now routinely polar body biopsies?
A. They are being, I can't -- as far as I understand, they still can be obtained. I don't know if it's routine.
Q. Do you have an opinion as to whether or not Mark Hughes or Genesis should have offered polar body biopsy to the Grossbaums?
A. I have an opinion that he could have considered offering it as an alternate to -- to doing the testing.
Q. But you don't believe it was negligent for him --
A. No, I actually don't and that's why I have not

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mentioned it myself.
Q. Now, I don't know if I asked you for this, it is getting late in day. Does your lab at any time do polar body --
A. No, no, no, we don't.
Q. You do you agree that even today polar body biopsy is not a mainstream approach?
MR. STEIN: Mainstream, objection to form.
Q. In the United States, granted that you're not going to be all that familiar with the PGD community?
MR. STEIN: Approach to -- objection.
A. Certain conditions people would argue that it's a good application. I -- I -- it's a difficult question to answer. It -- it his comments aside. Could you ask that again and give it to me precisely.
Q. Okay.
A. See if I ask answer it as best I can.
Q. Yes. And I'll add -- well, first of all do you agree that even today polar body biopsy is not a mainstream approach in the PGD community in the United States?
MR. STEIN: Same objection.
Q. Okay. Noted. Go ahead and answer the question.
A. So, the single cell analysis it is an option

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but it is the major one, no, it is an option so it is there.
Q. Okay. Do you expect to offer any opinions in this case as to the existence of a causal relationship between the action or failure to act by any of the defendants and the misdiagnosis or failure that occurred?
A. Yes.
Q. All right. Do you expect to offer such opinion as to Dr. Hughes, just yes or no?
A. Yes.
Q. Do you agree that because of the many variables involved in PGD, the cause or causes of PGD misdiagnosis are always difficult to pin down?
A. Say that again.
Q. Do you agree because of the many variables involved in PGD, and we've discussed some of them, potential mislabeling or --
A. Right.
Q. -- transaction position of things --
A. Yes.
Q. -- et cetera, et cetera? The cause or causes of PGD misdiagnoses are always difficult to pin down?
A. Always difficult to pin down. I don't agree with that.

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Q. Generally difficult?
A. No, I don't agree.
Q. Can each of the following things be possible causes of failure or misdiagnosis of PGD mosaicism?
MR. STEIN: Are you talking in this case or abstractly?
A. In any case?
Q. Can they be possible causes of failure or misdiagnosis in PGD, generally?
A. Can they be?
Q. Yes.
A. Yes, mosaicism can be which leads to ADO which you need to detect.
Q. All right. What is mosaicism?
A. Mosaicism is the fact that the embryo -- the cells of the embryo contain different numbers of chromosomes or difficult portions of the chromosomes. Instead of them having an entire compliment of 46 chromosomes they my make additional amounts or subset and some of the cells have it and some of them don't, so it's mosaic. So ...
Q. As of 2004 was it possible to predict mosaicism with any degree of medical probability?
A. Mosaicism had been recognized as a condition seen in egg cell embryos and in animals decades ago,

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and humans also.
Q. Okay.
A. It was known --
Q. It was know that it occurs --
A. Okay.
Q. -- in any given case --
A. Yes.
Q. -- was it possibly to predict mosaicism?
A. Predict whether mosaicism was there or appreciate that it could be there?
Q. Predict in a given case that it could --
A. Well, sure if you aggregated the entire embryo and test each one of them, yeah, you could show --
Q. But that isn't done?
A. Well, you could take two of the cells and that was shown when you take two cells that there was mosaicism. So this I was known by 2004.
Q. As PGD was practiced was it -- was it possible to predict mosaicism more likely than not?
A. It was reasonable to expect that it would -- it could potentially complicate the case, yes. That's about as far as I can go. I don't know where you're going with this question.
Q. Was mosaicism possible, not necessarily a probable or the probable but --

EXHIBIT 5

Weill Cornell Medical College

NewYork-Presbyterian Hospital
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Associate Professor

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February 26, 2010

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave.
Detroit, MI 48207

RE: Grossbaum v. Genesis Genetics & Hughes

Dear Mr. Leuchtman,

Per your request, I have reviewed the following documents which you sent to me:

1) Medical Records of Genesis Genetics
2) Medical Records of IVF Center of New York University Medical Center
3) Reports from Dr. Garry R, Cutting and Dr. Charles M. Strom
4) Depositions of Mark R. Hughes, MD, PhD, Genesis Genetics; and Frederick Licciardi, MD, James Grifo, MD, PhD; Ms Alexis Adler, Kaycian Brown, R.N.; and Ms. Imelda Weill, New York University Medical Center
5) Depositions of Chaya Grossbaum (Volume 1 and 2) and Menachem M. Grossbaum.

As I understand, both Chaya Grossbaum and Menachem M. Grossbaum are carriers of a mutation for cystic fibrosis gene. They were referred to NYU IVF center and underwent IVF and biopsy at NYU and the specimens were sent and analyzed by Genesis Genetics. The child born from the procedure was found be affected with cystic fibrosis.

As you probably know, I have been involved in PGD since 1992 when I was recruited as a faculty member at Cornell Medical College. I have published number of papers in PGD. For example, in 1993 we studied a new procedure, call Primer Extension Preamplification (PEP) for single human blastomeres. In particular we tested the most common CF mutation, delta F508, in the amplified products (Human Reproduction, 1993vol.8, No.12, pp2206-2210). In 1999, we published the first successful PGD case for sickle cell anemia (JAMA). Again in 2004, first PGD for retinoblastoma was reported in American Journal of Ophthalmology. Furthermore, I am a certified laboratory directory by ABB (American Board of Bioanalysis) since 2002 and by New York State Department of Health as laboratory director since Oct. 5, 2004. My laboratory, Laboratory of Preimplantation Genetics, Center for Reproductive Medicine and Infertility, Weill Medical College of Cornell University, obtained permit for performing PGD for molecular testing since March 2006 and for

cytogenetics, since 2007. Beginning from 1995, as I was the head of the PGD program and later as the director of the laboratory at the Center for Reproductive Medicine and Infertility, Weill Cornell Medical College. We have completed over 1300 cases of PGD for variety of indications, including more than 70 cases for cystic fibrosis, covering more than a dozen of CF mutations.

Having known Dr. Mark Hughes as many years as I have been involved in PGD, he is, without any doubt, one of the most renowned pioneers in Preimplantation Genetic Diagnosis. He was the coauthor of the very first paper in the scientific literature described the success of PGD for cystic fibrosis (1992, New England Journal of Medicine). He was a member of President Bioethics Council that described the importance of PGD and recommended funding for PGD research in 1994. It is definitely not trivial that he was recognized and highly praised by the Jewish community, Bonei Olem, for his contribution to PGD (see Dr. Licciardi's deposition, page 25).

An open question and a central issue in PGD is that PGD has its limitations because it is a single cell based test. It has been recognized in the beginning of last decade in the PGD community that allele drop out (ADO), which occurs when low DNA copy numbers are used as the starting material for genetic testing, is a challenging issue. Numerous papers have been published in order to reduce or eliminate this inherent risk. Some proposed to biopsy two cells from one embryo, others tested different lysis strategies; still others were trying to use whole genome amplification to obtain more DNA for replicate testing. None of them appears to be fully effective. Current understanding is that ADO is a very complicated matter and there may be many contributing factors. ADO varies from cell type to cell type. ADO is usually low in the healthy cells, such as lymphocytes and fibroblast cells harvested at the growth phase. Likewise in blastomeres, ADO may also vary according the healthy status of the cells/embryos. It is not unreasonable that a healthy diploid blastomere (D3, 7-9 cell stages) provide lowest chance of ADO. Indeed, we have seen more aneuploidy/mosaicism in those slow developing or arrested embryos (4-5 cells on the morning of Day-3 post fertilization) in our FISH based aneuploidy tests.

Accumulated knowledge from the Human Genome Project facilitates the use of linkage markers which may reduce substantially the risk of ADO. Though it is highly desirable, markers are not always used even as of today for various reasons. Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome dominant disorder with 50% risk without using markers. The reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 diferent IVF-PGD attempts. I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.

The tests performed on July 18-19, 2004 did statistically reduce the risk, from 25% to a much lower percentage. It was proper to recommend the transfer of embryo #7 and 8 based upon both reports issued by Dr. Hughes and Genesis Genetics on July 19, 2004. Results in both of Dr. Hughes' reports prepared on July 19, 2004 were within the accepted level of risk and the level of risk agreed to by the patients.

Another issue of embryological work using polar body biopsy is open for debate. Polar body biopsy or preconception genetic diagnosis was reported in 1990. However, the use of polar body biopsy has been limited in a few laboratories around the world. A few laboratories that performing polar body biopsy, such as those in Germany and Italy, not because of its superior strategy but because of their

country's law. As of today polar body biopsy for PGD is yet to be a mainstream approach (see a most recent debate article by Geraedts et al. Human Reproduction, 2010, v25, pp575). It was not its technical difficult, but with its real benefits in routine PGD. If one looks ESHRE (European Society of Human Reproduction and Embrylogy) data collection from I to IX (the latest one), one could only find few cases PGD using polar bodies as testing materials. At CRMI, we performed PB biopsy in the late 90's for balanced translocation; the girl is now over 12 year old. Nevertheless, we have not, as most of the labs in the world, used PB biopsy as a routine procedure.

Because of the ever-present risk of ADO, and other risk factors inherent in PGD, CVS and amniocentesis are universally relied upon as a safety net in PGD. CVS has been shown to be very accurate. I know from my experience that Dr. Hughes and Genesis Genetics will not take on PGD of a couple if they will not agree in advance to CVS or amniocentesis; and this is appropriate and within accepted standards.

From the documents I reviewed I believe that the couple was well informed on many occasions that there were risks of misdiagnosis and they have signed at least two important PGD consents, one from NYU, and one from Hughes' team. Dr Hughes went all the details, as much as he could, with the couple. Specifically, and without going into every detail in the consent forms, the Grossbaums demonstrated an understanding that this is not a perfect technology, it is complicated, it is an experimental process, lowering the risk to zero is not realistic or possible, the technology can fail, and follow-up confirmation testing (in the form of CVS or amniocentesis) is necessary. The Grossbaums agreed to go forward in light of the risks and alternatives, and they agreed with both NYU and Genesis Genetics to undergo confirmation testing in the form of CVS or amniocentesis.

Because of so many variables involved in PGD, the cause(s) of PGD misdiagnosis is always difficult to pin down. Based on the literature most misdiagnosis is due to intercourse or unprotected sex. In a published data collection (ESHRE PGD consortium data collection VII: cycles from January to December 2004 with pregnancy follow-up to October 2005, Human Reproduction, 2008; Vol 23, No. 4, pp 741755), the best data collection and analysis in PGD community, the consortium stated on page 750 that "Eighteen misdiagnosis have been reported, 9 after PGD for PCR and 9 after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the PGD cycle could be responsible as any embryos generated in vivo would not be tested." With this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums.

In summary, I see a tragic case happened, not because of any negligence, but unfortunately because of the complexity and the limitations of the PGD technology and likely other confounding factors. Genesis Genetics did very professionally, and no deviations were seen from the standard of care.

Respectfully yours,

Kangpu Xu, Ph.D., HCLD.
Associate Professor
Director, Laboratory of Preimplantation Genetics
CRMI, Weill Cornell Medical College

EXHIBIT 6

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as *guardians ad litem* of the infant ROSIE GROSSBAUM, Plaintiffs, -vs- GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPS. 1-10, JOHN DOES 1-10, Defendants.	CIVIL ACTION NO. 07-CV-1359 (GEB)(ES) **DECLARATION OF MARK R. HUGHES IN SUPPORT OF THE GENESIS DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

MARK R. HUGHES, being of full age, hereby declares as follows, pursuant to 28 U.S.C. § 1746:

1. I am a genetics research scientist specializing in studying the human genome of DNA and the technology of pre-implantation genetic diagnosis ("PGD"). I am also one of the principals of Genesis Genetics Institute, LLC, which is one of my co-defendants in this litigation.

2. I completed my B.S. in Biology and Chemistry at St. Johns University, and then earned an M.S. in molecular biophysics at Stanford University. I then completed my training a Ph.D. degree in Molecular Biochemistry from the University of Arizona. I then completed a postdoctoral fellowship in Medical Genetics at the Baylor College of Medicine in Houston, Texas, where I also earned my M.D. I completed my internship and residency in Internal Medicine at Duke University before returning to Baylor College of Medicine as a junior faculty member.

3. At Baylor, I researched the question of whether single cells could be molecularly data mined for diagnosis and began a multi-year collaboration with IVF clinicians and embryologists at Hammersmith Hospital in London, England. My colleagues in London and I were pioneers in the arena of PGD. Indeed, in 1993 our research was recognized by *Science* magazine, the most prestigious scientific journal, as being one of the "ten most significant advances" in all of science that year.

4. In 1993, I was one of the first 11 members of the Human Genome Institute at the National Institute of Health, where I led the section on Translational Genomic Diagnostics. I was also named Professor and Chair of the Human Genetics program at Georgetown University in Washington, DC.

5. In 1998, I accepted a position as a Professor and Director of Molecular Medicine and Genetics, Professor of Obstetrics and Gynecology, and a Professor of Pathology at Wayne State University, and a Senior Scientist at the Karmanos Cancer Institute. I also became

the Director of the State of Michigan's "Life Sciences Genomics Hub," which focused on developing cutting-edge molecular science.

6. In 2003, because of federal funding limitations on embryonic stem cell science, I founded Genesis Genetics Institute, LLC to provide PGD to IVF centers and reproductive endocrinologists.

7. Since the early 1990's, the focus of my research has been on developing techniques for pre-implantation genetic diagnosis both in a theoretical sense, as a genetic researcher, and in a practical sense, for providing practical applications of this research to families in which both partners have been diagnosed as carriers of genetic mutations that create a significant risk that their offspring will have serious genetic diseases. The purpose of PGD is to help couples reduce their risk of giving birth to offspring with devastating genetic diseases. The technology, however, is still new enough to be constantly evolving, and we fully inform every couple we work with that the technology, which pushes science to its practical and theoretical limits, is not error-free.

8. Despite the full disclosure I give to each couple Genesis works with about PGD technology's imperfections, during my entire career in the field of PGD, I have constantly monitored the scientific literature and best practices at the other laboratories that provide PGD as well as stayed active in PGD-related professional organizations and attended PGD-related conferences (often as a speaker, panelist, or other presenter) in an effort to ensure that the PGD services provided by the laboratories I have been associated with, including Genesis, have incorporated all proven technological advances into the services they offer to couples. I have also been a member in good standing of the Preimplantation Genetic Diagnosis International Society and President of the PGD-SIG of the American Society of Reproductive Medicine, the foremost organization in this field.

9. Because the PGD field is constantly evolving and changing, scientists are constantly publishing articles describing the latest technology trials. Publication of articles in the scientific literature describing a possible advance in PGD technology or techniques does not

dictate that the technology is proven or widely accepted, or that PGD laboratories will immediately change their standard practices. This includes any medical diagnostics: first, the published datas provided by the new technology or technique must be replicated repeatedly, over time; second, evidence must be collected demonstrating that the new technology or technique provides a significant benefit and no harm over the previous methodology; and finally, the technology or technique must be refined and adapted as necessary to be commercially viable. The length of time between publications and clinical implementation of a medical technique often requires several years.

10. In 2004, Genesis was not performing multiplex DNA amplification of genomic markers for clinical PGD. We had seen the results published by RGI of Chicago, but we had trouble replicating these data in our laboratory. Furthermore, our error rate without using multiplex markers was significantly lower than the industry average reported error rate. Finally, while we were aware that RGI in Chicago was providing multiplex testing to couples at the time, we agreed with Dr. Xu and others that the evidence did not yet support offering multiplex testing as the standard of care.

11. At his deposition, Dr. Charles Strom identified laboratories that he said were performing PGD in early-to-mid 2004. The laboratories he identified were:

- "RGI in Chicago" (Strom Dep. at 112:7-8)
- "Reprogenetics in New Jersey" (Strom Dep. at 112:15-16)
- "Genetics and I.V.F. in Virginia" (Strom Dep. at 112:18-20)
- "Cornell Medical Center in New York City" (Strom Dep. at 112:21-23).
- "Shady Grove" of "North Carolina" (Strom Dep. at 113:2-16)
- "Baylor" (Strom Dep. at 113:2-12)
- "a lab in Florida that was trying to develop P.G.D." (Strom Dep. at 113:9-12)

12. In fact, Dr. Strom's testimony betrays not only his lack of knowledge regarding the standard of care at United States PGD laboratories in 2004, but also displays that

he was not even aware of which laboratories were performing PGD at that time. For instance, Shady Grove (of Washington, D.C., not North Carolina) was not independently performing PGD for disorders like Cystic Fibrosis in 2004, but instead was sending all of its PGD work to Genesis Genetics.

13. From my active participation in the PGD community and interaction with professionals at these institutions, I am familiar with the practices of these laboratories in the 2004 time frame. To the best of my knowledge, in July of 2004, when Genesis performed its study of the Grossbaums' embryos, the only United States laboratory that routinely offered multiplex testing to its patients was RGI of Chicago, Illinois. In particular, from my previous association with the Prenatal Genetics Center at Baylor, I am aware that Baylor was not routinely providing multiplex testing in early-to-mid 2004.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 11, 2011

Mark R. Hughes, M.D., Ph.D

EXHIBIT 7

ENTERED

Page: 1
Date: 2004 - 03 (Month) - 25 (Day)

Pre-Case Phone Review of PGD Informed Consent

Last Name: Margenstern-Grossbaum Disorder: Cystic Fibrosis

Patient's First: Chaya [ ] Man's First: Menachem [ ] Affected's First: =

Referred By: Siccardi IVF Program: NYU-IVF

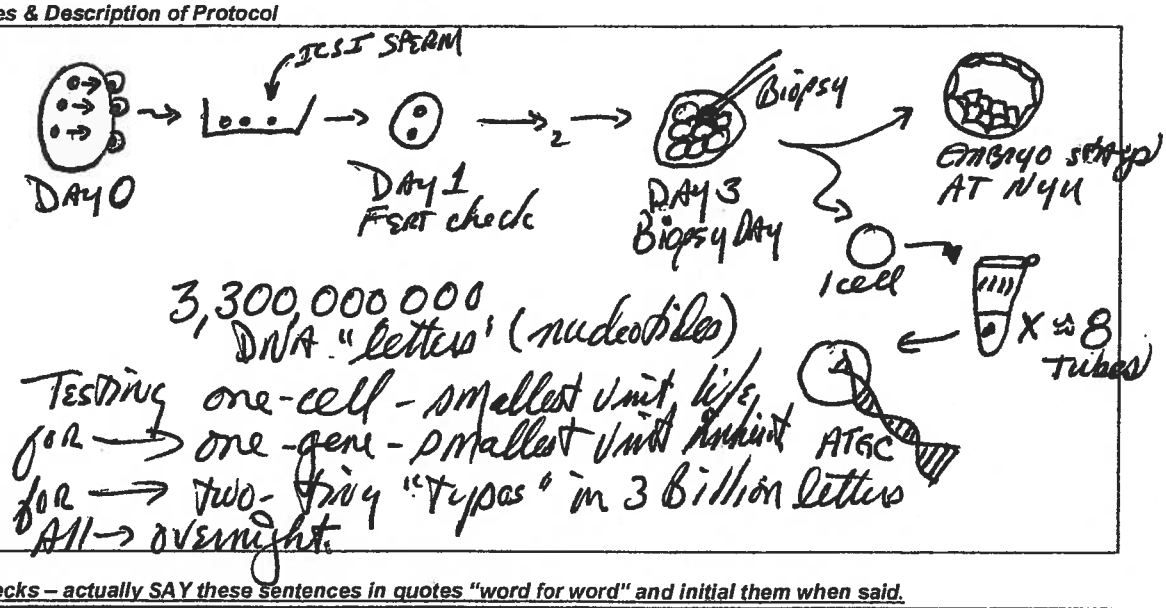
▶Infertility ___ Y X N X? ▶IVF Before: ___ Y X N ▶Blood Here: 3/30/04 Date ___ N

no pregnancies

Chaya has G542X & Menachem has ΔF508 mutations

Example of numerical outcomes & Description of Protocol

Eggs Retrieved ~ 6+6=12
Eggs Fertilized ~ 10
Embryos To Biopsy ~ 8
Genetic Results Est ~ 8
MM ~ 2
MN ~ 4 → 6
NN ~ 2



Summary of Conversation Checks – actually SAY these sentences in quotes "word for word" and initial them when said.

MRM Protocol Description: A detailed, step-by-step, description of PGD was described. In addition, this couple X has X has not, also seen a geneticist / genetic counselor, who is an independent source of medical information about this disease, and the options available to them.

MRM Genesis Involvement: "We are not your physicians." "We are scientists who will try to develop a complicated single-cell test for your family so that Preimplantation Genetic Diagnosis can be used." This will involve: X designing new DNA probes; ___ using existing probes in your care.

MRM Risks Described. "This is not perfect technology." "This is an experimental process." "There have been errors by virtually all groups performing this technology, including our group". "The objective here is to lower your risk from 25 %, but lowering it to zero is not realistic or possible."

MRM "It is important that you understand that technology like this can fail." 'zero risk' is not expected, not promised and not possible in one-cell, one-gene, one/two DNA typo, overnight testing". "It would not be truthful to suggest that we are perfect or that this technology has not produced errors – neither is true"

MRM Alternative Treatments. "You do not need preimplantation genetic diagnosis. You can get pregnant and assume the risks that are inherent to this disease."

MRM Follow-up Confirmation Testing: "Because single cell testing, overnight, pushes diagnostic technology to its limits – theoretical and practical – it is imperative that should a pregnancy ensue, conventional prenatal testing (chorionic villus sampling at around 10 weeks, or amniocentesis around 15-16 weeks is necessary. Maternal fetal medicine doctors will perform this testing for you."

MRM Affected / Non-transferred Embryos: The choices available explained. They should discuss this with the Reproductive Endocrinologist as well. Donation to medical research is a possibility to consider. Couple ____ agrees; ____disagrees; ___not sure yet, that donation is the choice they prefer; X not discussed during this particular conversation.

MRM The couple indicates that all of their questions at this juncture have been answered. They want to: ___Think about this more: ___Use an alternative approach to building their family (X Have us design/optimize DNA probes to their mutation for PGD.

MRM "Are all your questions answered". Offered to be available to answer any question they have in the future. Email / Phone number provided.

☐ ~~Photograph~~

"YES - Thank you" MG Mark Hughes Both

Page: 2
Date: 3-25-04
Last Name: MORGANSTERN

Phone notes continued

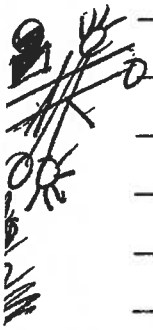
→ No history of infertility (but no children either.)
Rabbi Jacob - (something) referred us to Nyn.

No apparent history of CF in either family pedigree. This was found with a routine Jewish screen*

You do not need PGD. Remember - you can just get pregnant & have a prenatal test like "CVS or Amnio". There are great OB docs in NYC who Ed. could do this for yo

"We do not like those odds" (MG)

This is complicated. Two different mutations tested simultaneously, in one cell. Details explained.
Chaya → 11th sentence, 542 'word', 1756 letter G>T
Mandel → 10th a ; 508 'word', 1652 letter → CTT missing



G>T CTT>del CTT

N/N	N/M	N/M	M/M
Normal noncarrier		carrier like mom & DAD	Affected
G/CTT	G/delCTT or T/CTT		T/delCTT
Normal	carrier		Affected
1/4	+ 2/4	+	1/4 = 4/4

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We would design custom test for you –
→ your DNA is unique on the planet
→ the DNA you mix together to make a baby is unique.
→ Every time you do that it is different & unique
→ The test is special too.
✓ This is not routine care
✓ Your test will be optimized just for you.
✓ There have been errors in PGD in the past even in CF testing. We've had 11 errors in 14 years in hundreds of families. It is awful when it does. I'm not so arrogant as to tell you I am perfect or we can make a perfect test. Med is not a perfect science. "Art" of medicine. Need to follow-up with CVS or amnio - (EVANS)? too.

? Blood possible from parents? Seems not.

The goal is to lower your risks – from 1-in-4 to much less. Not zero risk. The technology can fail too.
Some samples might not produce any gene data. Usually problem with embryo or the removal of cell.
→ We won't be testing chromosomes here. They will look at the chromosomes when you have your prenatal confirmatory test.

Yes

Biopsy Risk –
None known v. Could ↓ implantation
just like freezing embryos.
No evidence of ↑ birth defects

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(then went to)

Embryo donation – Think about this more. Good.
We support whatever decisions you make
We would study the affected ones
to make a better test for you for
the future. Need technology is
coming along now.

PLANS = 1) They state clearly they understand the process – its success + risks

2) They would like to proceed ASAP → summer?

3) They want us to design their a mutation test to help them build a healthy family by lowering the odds of CF in a baby

* 4) Need blood samples.
Contact Nyu
No guarantees here.
Going for you → probably not infertile. (Great)
Going against you → some nice looking embryos will probably have CF.

5) Order oligos/primers.
Test DNA when arrives
Optimize test to 1 cell
START IVF when ready.